Because uropathogens on vaginal cells...

New *in vitro* studies indicate specific *E.coli* receptors on the urogenital epithelium may be an important factor in recurrent infection.

Researchers have recently identified a chemical receptor for *E. coli* on the uroepithelial cells of women who are subject to recurrent urinary tract infections.[1]

The receptor is a glycosphingolipid known as α-D-Gal*p* (1→4)-β-D-Gal*p*. This carbohydrate is an antigen found on the red blood cells and the uroepithelial cells of women who have P-positive phenotypes.[1,2] It is *not* present on the erythrocytes or uroepithelial cells of women who are P-negative. Women who belong to the rare P-negative blood group had a much lower capacity for binding uropathogenic *E. coli* to their urogenital cells *in vitro* and had never experienced recurrent urinary tract infection. The cells from P-positive women, on the other hand, had a very high capacity for binding virulent *E. coli.* These women are generally much more likely to get recurrent infections. The chemical receptor appears to be a major factor responsible for this.[1]

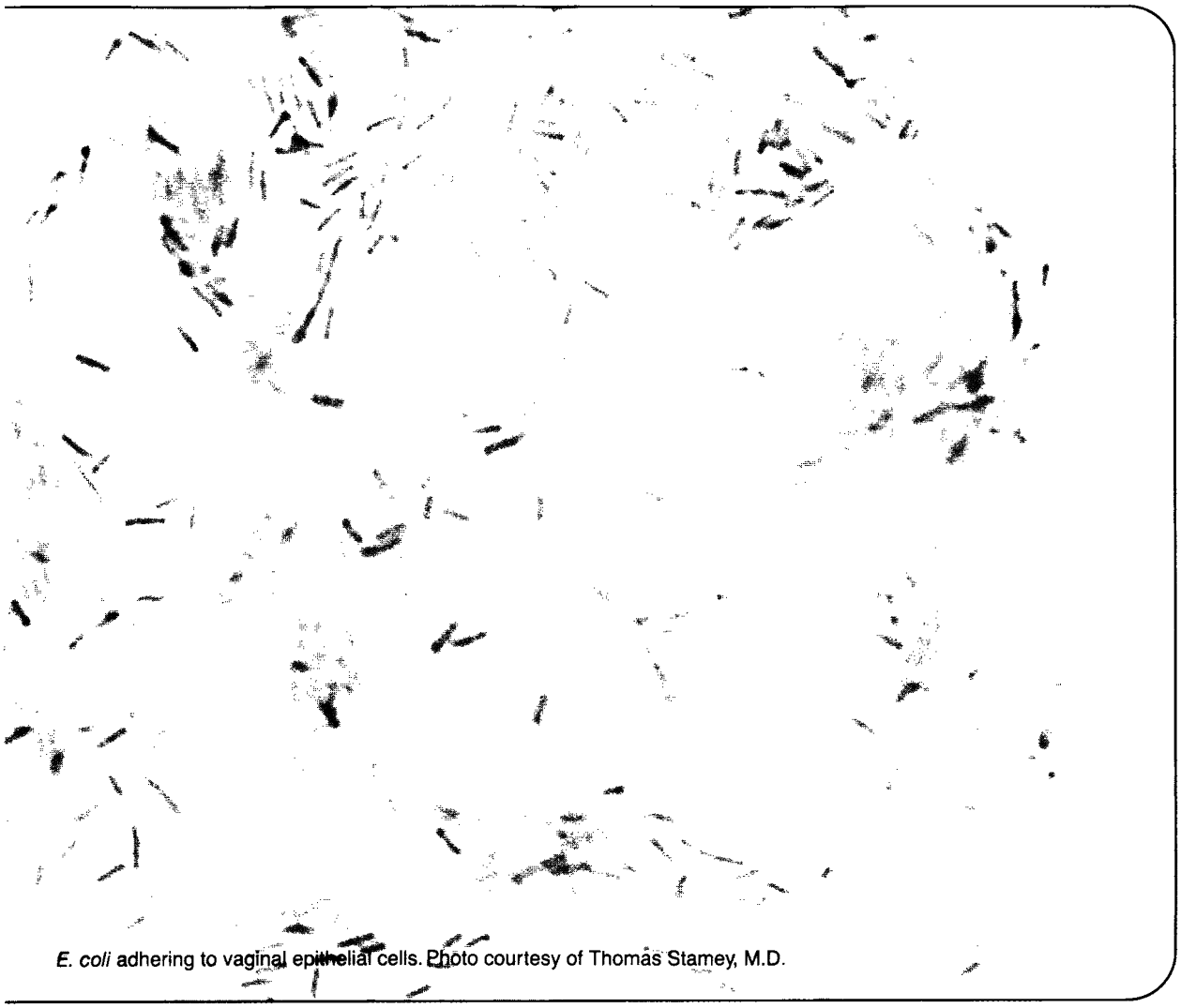
Adherence of *E.coli* to vaginal mucosal cells increases susceptibility to urinary infections.

Another study, comparing women who experienced three or more urinary tract infections per year with healthy controls, found that vaginal cells from the women with recurrent urinary infections had a greater tendency to bind *E. coli in vitro*—even when the cells were cultured while there was no infection. The researchers speculated that deficient host defense mechanisms in vaginal mucosal cells may be responsible for recurrent urinary infections in many women.[3] *E. coli* and other uropathogens may colonize the vaginal introitus, adhere to receptors on mucosal cells and then infect the urinary tract.

Get to the source of recurrent urinary tract infection* with

*Due to susceptible organisms such as *E. coli, Klebsiella-Enterobacter* and *Proteus* species.

cling to receptors



E. coli adhering to vaginal epithelial cells. Photo courtesy of Thomas Stamey, M.D.

The pharmacologic and pharmacokinetic activities of Bactrim (trimethoprim and sulfamethoxazole/Roche) make it particularly appropriate for the treatment of recurrent urinary infections.* The vast majority of *E. coli* strains and a wide spectrum of other common uropathogens are susceptible to Bactrim *in vitro*.[4] Bactrim achieves high concentrations in the urine, and the trimethoprim component diffuses into the vaginal area and attacks susceptible uropathogens that cling to mucosal cells.[5] In the fecal flora, Bactrim suppresses Enterobacteriaceae,[6] with little resulting emergence of resistant organisms. Bactrim is contraindicated in pregnancy at term, nursing mothers, infants under two months of age and documented megaloblastic anemia due to folate deficiency.

Bactrim DS. Twice a day for 10 to 14 days in recurrent urinary tract infections.*

*Due to susceptible organisms such as *E. coli, Klebsiella-Enterobacter* and *Proteus* species.

Bactrim™ DS

(trimethoprim and sulfamethoxazole/Roche)

Economical and effective *b.i.d.* therapy.

See next page for references and a summary of product information.

References: 1. Källenius G *et al: Lancet 2*:604-606, Sep 19, 1981. **2.** Lomberg H *et al: Lancet 1*:551-552, Mar 7, 1981. **3.** Schaeffer AJ *et al: N Engl J Med 304*:1062-1066, Apr 30, 1981. **4.** BacData Medical Information Systems: *Antibiotic Sensitivity Report,* Winter Series, 1981. **5.** Stamey TA, Condy M: *J Infect Dis 131*:261-266, Mar 1975. **6.** Rubin RH, Swartz MN: *N Engl J Med 303*:426-431, Aug 21, 1980.

WE HAVE A SOLUTION FOR A DIFFICULT UROLOGICAL PROBLEM

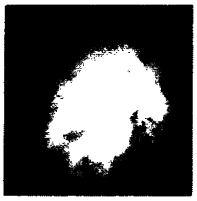
The Problem

SYMPTOMS:

EARLY
INTERSTITIAL CYSTITIS

- ☐ irritative voiding symptoms
- ☐ suprapubic pain
- ☐ functional bladder capacity reduced
- ☐ anatomical bladder capacity:
  - EARLY — normal
  - CLASSICAL — reduced

CLASSICAL
INTERSTITIAL CYSTITIS

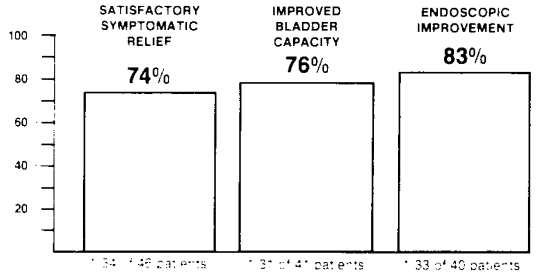


- ☐ vesical mucosa:
  - EARLY — normal appearing
  - CLASSICAL — ulcerated, scarred
- ☐ submucosal vesical hemorrhages observed following second overdistension

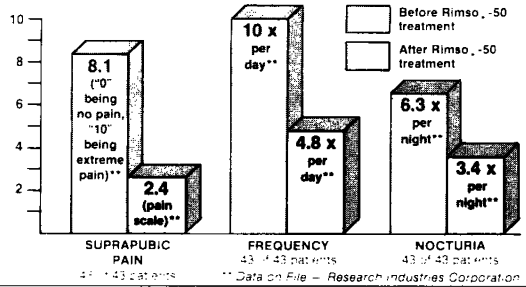
DIAGNOSIS: INTERSTITIAL CYSTITIS

The Solution

Rimso-50®
brand of
STERILE AND PYROGEN-FREE DIMETHYL SULFOXIDE



*STEWART, B.H., et al., J. Urol., 36:116, 1976



** Data on File — Research Industries Corporation

FOR FURTHER INFORMATION WJ3/83

RESEARCH INDUSTRIES CORPORATION
1847 West 2300 South
Salt Lake City, Utah 84119
Toll-Free 1-800-453-8432

Name

Address

City State Zip

Rimso®-50
(dimethyl sulfoxide)
50% w/w aqueous solution

INDICATIONS AND USAGE: Rimso®-50 (dimethyl sulfoxide) is indicated for the symptomatic relief of patients with interstitial cystitis. Rimso®-50 has not been approved as being safe and effective for any other indication. There is no clinical evidence of effectiveness of dimethyl sulfoxide in the treatment of bacterial infections of the urinary tract.
CONTRAINDICATIONS: None known.
WARNINGS: Dimethyl sulfoxide can initiate the liberation of histamine and there has been occasional hypersensitivity reaction with topical administration of dimethyl sulfoxide. This hypersensitivity has been reported in one patient receiving intravesical Rimso®-50. The physician should be cognizant of this possibility in prescribing Rimso®-50. If anaphylactoid symptoms develop, appropriate therapy should be instituted.
PRECAUTIONS: Changes in the refractive index and lens opacities have been seen in monkeys, dogs and rabbits given high doses of dimethyl sulfoxide chronically. Since lens changes were noted in animals, full eye evaluations, including slit lamp examinations, are recommended prior to and periodically during treatment. Approximately every six months patients receiving dimethyl sulfoxide should have a biochemical screening, particularly liver and renal function tests, and complete blood count.

Intravesical instillation of Rimso®-50 may be harmful to patients with urinary tract malignancy because of dimethyl sulfoxide-induced vasodilation. Some data indicate that dimethyl sulfoxide potentiates other concomitantly administered medications.

Pregnancy Category C. Dimethyl sulfoxide caused teratogenic responses in hamsters, rats and mice when administered intraperitoneally at high doses (2.5-12 gm/kg). Oral or topical doses of dimethyl sulfoxide did not cause problems of reproduction in rats, mice and hamsters. Topical doses (5 gm/kg first two days, then 2.5 gm/kg - last eight days) produced teratoma in rabbits, but in another study, topical doses of 1.1 gm/kg days 3 through 16 of gestation failed to produce any abnormalities. There are no adequate and well controlled studies in pregnant women. Dimethyl sulfoxide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dimethyl sulfoxide is administered to a nursing woman.

Safety and effectiveness in children have not been established.
ADVERSE REACTIONS: A garlic-like taste may be noted by the patient within a few minutes after instillation of Rimso®-50 (dimethyl sulfoxide). This taste may last several hours and because of the presence of metabolites an odor on the breath and skin may remain for 72 hours.

Transient chemical cystitis has been noted following instillation of dimethyl sulfoxide. The patient may experience moderately severe discomfort on administration. Usually this is becomes less prominent with repeated administration.
DOSAGE AND ADMINISTRATION: Instillation of 50 ml of Rimso®-50 (dimethyl sulfoxide) directly into the bladder may be accomplished by catheter or asepto syringe and allowed to remain for 15 minutes. Application of an analgesic lubricant gel such as dibucaine jelly to the urethra is suggested prior to insertion of the catheter to avoid spasm. The medication is expelled by spontaneous voiding. It is recommended that the treatment be repeated every two weeks until maximum symptomatic relief is obtained. Thereafter, time intervals between therapy may be increased appropriately.

Administration of oral analgesic medication or suppositories containing belladonna and opium prior to the instillation of Rimso®-50 can reduce bladder spasm.

In patients with severe interstitial cystitis with very sensitive bladders, the initial treatment and possibly the second and third (depending on patient response) should be done under anesthesia. (Saddle block has been suggested.)
HOW SUPPLIED:
Bottles contain 50 ml of sterile and pyrogen-free Rimso®-50 (50% w/w dimethyl sulfoxide aqueous solution).
Dimethyl sulfoxide is clear and colorless.
Protect from strong light.
Store at room temperature (15° to 30° C).
Do not autoclave.
NDC #0433-0433-05

*Stewart, B.H., et al., J. Urol., 36:116, 1976

Rimso®-100

brand of
STERILE AND PYROGEN-FREE DIMETHYL SULFOXIDE

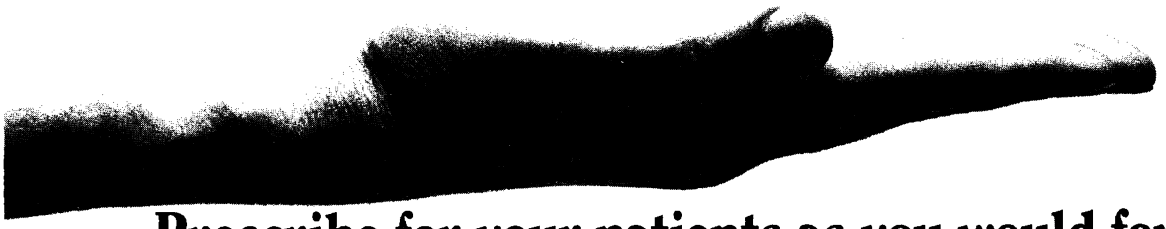
CRYOPRESERVATIVE SOLUTION
(99.0 + concentration)

Available in:

10 ml ampules, 10 ampules case
70 ml bottles, 6 bottles case
70 ml multi-dose containers, 6 bottles case

There's more to ZYLOPRIM® than (allopurinol).

- From Burroughs Wellcome Co. – the discoverer and developer of allopurinol
- Patient starter/conversion kits available for easy titration of initial dosage
- Patient compliance pamphlets available
- Continuing medical education materials available for physicians



Prescribe for your patients as you would for yourself.

Write "D.A.W.," "No Sub," or "Medically Necessary," as your state requires, to make sure your patient receives the original allopurinol.

Wellcome / **Burroughs Wellcome Co.**
Research Triangle Park
North Carolina 27709

CAPOTEN® TABLETS
Captopril Tablets

INDICATIONS: Hypertension — Because serious adverse effects have been reported (see WARNINGS), CAPOTEN is indicated for treatment of hypertensive patients who on multidrug regimens have either failed to respond satisfactorily or developed unacceptable side effects.

Heart Failure: CAPOTEN (captopril) is indicated in patients with heart failure who have not responded adequately to or cannot be controlled by conventional diuretic and digitalis therapy. CAPOTEN is to be used with diuretics and digitalis.

WARNINGS: Proteinuria — Total urinary proteins >1 g/day were seen in 1.2% of patients on captopril; the nephrotic syndrome occurred in about ¼th of these cases. About 60% of affected patients had evidence of prior renal disease; the remainder had no known renal dysfunction. In most cases, proteinuria subsided or cleared within 6 months whether or not captopril was continued. The BUN and creatinine were seldom altered in proteinuric patients.

Membranous glomerulopathy was found in nearly all the proteinuric patients on captopril who were biopsied and may be drug related. Most cases of proteinuria occurred by the 8th month of therapy. Patients should have urinary protein estimates (dip-stick on 1st morning urine, or quantitative 24-hr urine — the latter provides greater precision when proteinuria is persistent and/or at low levels) before therapy, at approx. monthly intervals for the 1st 9 months of therapy, and periodically thereafter. For patients who develop proteinuria >1 g/day, or increasing proteinuria, the benefits and risks of continuing captopril should be evaluated.

Neutropenia/Agranulocytosis — Neutropenia (<300/mm³) associated with myeloid hypoplasia (probably drug related) occurred in about 0.3% of captopril treated patients. About half of the neutropenic patients developed systemic or oral cavity infections or other features of agranulocytosis. Most of the neutropenic patients had severe hypertension and renal function impairment; about half had systemic lupus erythematosus (SLE), or another autoimmune/collagen disorder; multiple concomitant drug therapy was common, including immunosuppressive therapy in a few cases. Daily doses of captopril in the leukopenic patients were relatively high, particularly in view of their diminished renal function. The neutropenia appeared 3 to 12 weeks after starting captopril; it developed relatively slowly, taking 10 to 30 days to have white blood count fall to its nadir; neutrophils returned to normal in about 2 weeks (other than 2 patients who died of sepsis).

Use captopril with caution in patients with impaired renal function, serious autoimmune disease (particularly SLE), or who are exposed to other drugs known to affect the white cells or immune response. In patients at particular risk (as noted above), perform white blood cell and differential counts prior to therapy, at about 2-week intervals for about the 1st 3 months of therapy, and periodically thereafter.

The risk of neutropenia in patients who are less seriously ill or who receive lower dosages appears to be smaller. In these patients white blood cell counts should be performed every 2 weeks for the 1st 3 months of therapy, and periodically thereafter. Perform differential counts when leukocytes are <4000/mm³ or the pretherapy white count is halved. All patients treated with captopril should be told to report any signs of infection (e.g., sore throat; fever); if infection is suspected, perform counts without delay. Since discontinuation of captopril and other drugs has generally led to prompt return of the white count to normal, upon confirmation of neutropenia (neutrophil count <1000/mm³) withdraw captopril and closely follow the patient's course.

Hypotension — Excessive hypotension was rarely seen in hypertensive patients but is a possibility in severely salt/volume-depleted persons such as those treated vigorously with diuretics (see PRECAUTIONS [Drug Interactions]).

In heart failure, where blood pressure was either normal or low, transient decreases in blood pressure >20% were recorded in about ½ the patients. This transient hypotension may occur after any of the first several doses and is usually well tolerated, although rarely it has been associated with arrhythmia or conduction defects. A starting dose of 6.25 or 12.5 mg tid may minimize the hypotensive effect. Patients should be followed closely for the first 2 weeks of treatment and whenever the dose of captopril and/or diuretic is increased.

BECAUSE OF THE POTENTIAL FALL IN BLOOD PRESSURE IN THESE PATIENTS, THERAPY SHOULD BE STARTED UNDER VERY CLOSE MEDICAL SUPERVISION.

PRECAUTION: General: *Impaired Renal Function,* Hypertension — Some hypertensive patients with renal disease, particularly those with severe renal artery stenosis, have developed increases in BUN and serum creatinine. It may be necessary to reduce captopril dosage and/or discontinue diuretic. For some of these patients, normalization of blood pressure and maintenance of adequate renal perfusion may not be possible. Heart Failure — About 20% of patients develop stable elevations of BUN and serum creatinine >20% above normal or baseline upon long-term treatment. Less than 5% of patients, generally with severe preexisting renal disease, required discontinuation due to progressively increasing creatinine. See DOSAGE AND ADMINISTRATION, ADVERSE REACTIONS [Altered Laboratory Findings]. *Valvular Stenosis* — A theoretical concern, for risk of decreased coronary perfusion, has been noted regarding vasodilator treatment in patients with aortic stenosis, due to decreased afterload reduction.

Surgery/Anesthesia — If hypotension occurs during major surgery or anesthesia, and is considered due to the effects of captopril, it is correctable by volume expansion.

Drug Interactions: *Hypotension: Patients on Diuretic Therapy* — Precipitous reduction of blood pressure may occasionally occur within the 1st 3 hours after administration of the initial captopril dose in patients on diuretics, especially those recently placed on diuretics and those on severe dietary salt restriction or dialysis. This possibility can be minimized by either discontinuing the diuretic or increasing the salt intake about 1 week prior to initiation of captopril therapy. Alternatively, provide medical supervision for at least 3 hours after the initial dose in hypertensive patients.

Agents Having Vasodilator Activity: In heart failure patients vasodilators should be administered with caution.

Agents Causing Renin Release — Captopril's effect will be augmented by antihypertensive agents that cause renin release.

Agents Affecting Sympathetic Activity — The sympathetic nervous system may be especially important in supporting blood pressure in patients receiving captopril alone or with diuretics. Beta-adrenergic blocking drugs add some further antihypertensive effect to captopril, but the overall response is less than additive. Therefore, use agents affecting sympathetic activity (e.g., ganglionic blocking agents or adrenergic neuron blocking agents) with caution.

Agents Increasing Serum Potassium — Give potassium-sparing diuretics or potassium supplements only for documented hypokalemia, and then with caution, since they may lead to a significant increase of serum potassium.

Drug/Laboratory Test Interaction: Captopril may cause a false-positive urine test for acetone.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Two-year studies with doses of 50 to 1350 mg/kg/day in mice and rats failed to show any evidence of carcinogenic potential. Studies in rats have revealed no impairment of fertility.

Usage in Pregnancy: There are no adequate and well-controlled studies in pregnant women. Embryocidal effects were observed in rabbits. Therefore, captopril should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

Nursing Mothers: Captopril is secreted in human milk. Exercise caution when administering captopril to a nursing woman, and, in general, nursing should be interrupted.

Pediatric Use: Safety and effectiveness in children have not been established although there is limited experience with use of captopril in children from 2 months to 15 years of age. Dosage, on a weight basis, was comparable to that used in adults. Captopril should be used in children only if other measures for controlling blood pressure have not been effective.

ADVERSE REACTIONS: Reported incidences are based on clinical trials involving about 4000 patients.

Renal — One to 2 of 100 patients developed proteinuria (see WARNINGS). Renal insufficiency, renal failure, polyuria, oliguria, and urinary frequency in 1 to 2 of 1000 patients.

Hematologic — Neutropenia/agranulocytosis occurred in about 0.3% of captopril treated patients (see WARNINGS). Two of these patients developed sepsis and died.

Dermatologic — Rash (usually mild, maculopapular, rarely urticarial), often with pruritus and sometimes with fever and eosinophilia, in about 10 of 100 patients, usually during the 1st 4 weeks of therapy. Pruritus, without rash, in about 2 of 100 patients. A reversible associated pemphigoid-like lesion, and photosensitivity have also been reported. Angioedema of the face, mucous membranes of the mouth, or of the extremities in about 1 of 100 patients — reversible on discontinuance of captopril therapy. One case of laryngeal edema reported. Flushing or pallor in 2 to 5 of 1000 patients.

Cardiovascular — Hypotension in about 2 of 100 patients. See WARNINGS (Hypotension) and PRECAUTIONS (Drug Interactions) for discussion of hypotension on initiation of captopril therapy. Tachycardia, chest pain, and palpitations each in about 1 of 100 patients. Angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure each in 2 to 3 of 1000 patients.

Dysgeusia — About 7 of 100 patients developed a diminution or loss of taste perception; taste impairment is reversible and usually self-limited even with continued drug use (2 to 3 months). Gastric irritation, abdominal pain, nausea, vomiting, diarrhea, anorexia, constipation, aphthous ulcers, peptic ulcer, dizziness, headache, malaise, fatigue, insomnia, dry mouth, dyspnea, and paresthesias reported in about 0.5 to 2% of patients but did not appear at increased frequency compared to placebo or other treatments used in controlled trials.

Altered Laboratory Findings: Elevations of liver enzymes in a few patients although no causal relationship has been established. Rarely cholestatic jaundice and hepatocellular injury with secondary cholestasis have been reported. A transient elevation of BUN and serum creatinine may occur, especially in volume-depleted or renovascular hypertensive patients. In instances of rapid reduction of longstanding or severely elevated blood pressure, the glomerular filtration rate may decrease transiently, also resulting in transient rises in serum creatinine and BUN. Small increases in serum potassium concentration frequently occur, especially in patients with renal impairment (see PRECAUTIONS).

OVERDOSAGE: Primary concern in correction of hypotension. Volume expansion with an I.V. infusion of normal saline is the treatment of choice for restoration of blood pressure. Captopril may be removed from the general circulation by hemodialysis.

DOSAGE AND ADMINISTRATION: CAPOTEN should be taken one hour before meals. Dosage must be individualized; see DOSAGE AND ADMINISTRATION section of package insert for detailed information regarding dosage in hypertension and in heart failure. Because CAPOTEN (captopril) is excreted primarily by the kidneys, dosage adjustments are recommended for patients with impaired renal function.

Consult package insert before prescribing CAPOTEN (captopril).

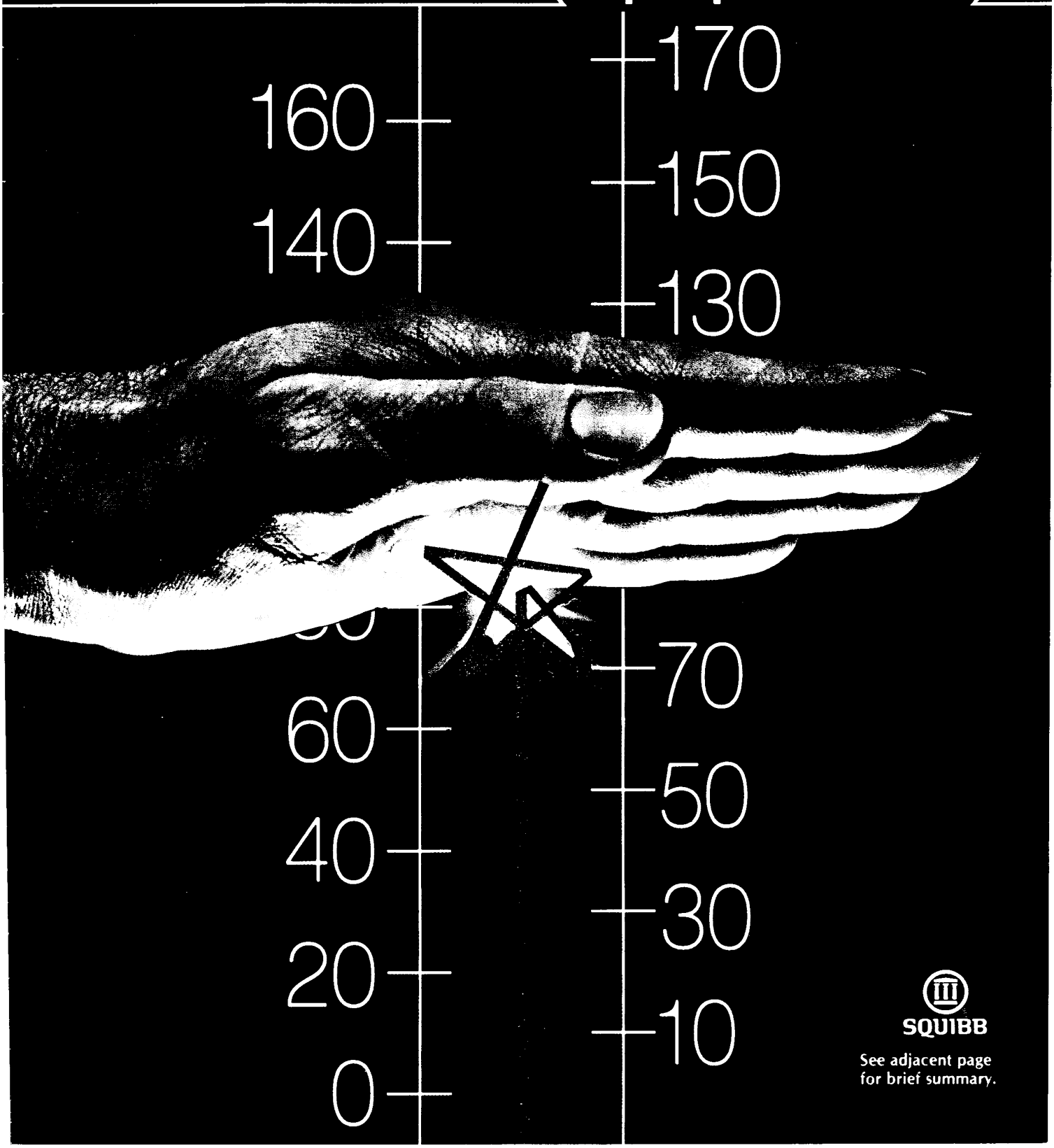
HOW SUPPLIED: Available in tablets of 25, 50, and 100 mg in bottles of 100, and in UNIMATIC® unit-dose packs of 100 tablets.

523-503

Issued: January 1983

Designed to achieve your therapeutic goals in hypertension

CAPOTEN® (captopril tablets)



SQUIBB

See adjacent page for brief summary.

Hypertension: A New Therapeutic Perspective.

A Symposium.

Program Chairman:
Norman Kaplan, M.D.
University of Texas
Health Science Center
Dallas, Texas

Participants:
Vincent DeQuattro, M.D.
University of Southern California
Medical Center
Los Angeles, California

Walter Flamenbaum, M.D.
Beth Israel Hospital
New York, New York

Charles K. Francis, M.D.
Yale University School of Medicine
New Haven, Connecticut

Ronald B. George, M.D.
Louisiana State University
School of Medicine
Shreveport, Louisiana

Paul MacCarthy, M.D.
University of Cincinnati
Medical Center
Cincinnati, Ohio

Jay Mehta, M.D.
University of Florida
Gainesville, Florida

Daniel Wilson, M.D.
Bowman-Gray School of Medicine
Winston-Salem, North Carolina

This Symposium takes place the day before the annual session of the American College of Physicians.

The Symposium will be preceded by a brunch at 12:00 noon, and there will be a cocktail reception from 5:00 to 7:00 pm immediately following the Symposium.

Sunday, April 10, 1983
1:00 p.m.
Sheraton Palace Hotel
San Francisco

Sponsored by Schering Corporation as a Continuing Medical Education Service

Schering

A familiar name in medicine;
a new name in cardiovascular therapy.

Qualifies for 4 hours Category I CME credit,
University of Texas, Health Science Center

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Let Ru-Tuss® Help Your "Stormy" Patient Come Closer to Spring

Prompt, effective treatment with Ru-Tuss® tablets offers welcome relief to winter-cold patients. Ru-Tuss® tablets ease congestion, relieve respiratory-tract itch and the need to sneeze.

RU-TUSS®
TABLETS

Each prolonged action tablet contains: Phenylephrine Hydrochloride 25 mg • Phenylpropanolamine Hydrochloride 50 mg • Chlorpheniramine Maleate 8 mg • Hyoscyamine Sulfate 0.19 mg • Atropine Sulfate 0.04 mg • Scopolamine Hydrobromide 0.01 mg • Each Ru-Tuss tablet acts continuously for 10 to 12 hours.

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- convenient b.i.d. dosage

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Pioneers in medicine for the family

Brief Summary of Prescribing Information (see attached)

Candidates for nutritional therapy...

10,000,000 alcoholics. Ethanol may produce many effects that together bring about nutritional deficiencies, so that alcoholism affects nutrition at many levels.[1]

25,500,000 geriatric patients. The older patient may have some disorder or socio-economic problem that can undermine good nutrition.[2]

23,500,000 surgical patients. Nutritional status can be compromised by the trauma of surgery; and some operations interfere with the ingestion, digestion and absorption of food.[3]

Before prescribing, please consult complete product information, a summary of which follows:
Each Berocca® Plus tablet contains 5000 IU vitamin A (as vitamin A acetate), 30 IU vitamin E (as *dl*-alpha tocopheryl acetate), 500 mg vitamin C (ascorbic acid), 20 mg vitamin B_1 (as thiamine mononitrate), 20 mg vitamin B_2 (riboflavin), 100 mg niacin (as niacinamide), 25 mg vitamin B_6 (as pyridoxine HCl), 0.15 mg biotin, 25 mg pantothenic acid (as calcium pantothenate), 0.8 mg folic acid, 50 mcg vitamin B_{12} (cyanocobalamin), 27 mg iron (as ferrous fumarate), 0.1 mg chromium (as chromium nitrate), 50 mg magnesium (as magnesium oxide), 5 mg manganese (as manganese dioxide), 3 mg copper (as cupric oxide), 22.5 mg zinc (as zinc oxide).

Indications: Prophylactic or therapeutic nutritional supplementation in physiologically stressful conditions, including conditions causing depletion, or reduced absorption or bioavailability of essential vitamins and minerals; certain conditions resulting from severe B-vitamin or ascorbic acid deficiency; or conditions resulting in increased needs for essential vitamins and minerals.
Contraindications: Hypersensitivity to any component.
Warnings: Not for pernicious anemia or other megaloblastic anemias where vitamin B_{12} is deficient. Neurologic involvement may develop or progress, despite temporary remission of anemia, in patients with vitamin B_{12} deficiency who receive supplemental folic acid and who are inadequately treated with B_{12}.
Precautions: *General:* Certain conditions may require additional nutritional supplementation. During pregnancy, supplementation with vitamin D and calcium may be required. Not intended for treatment of severe specific deficiencies. *Information for the Patient:* Toxic reactions have been reported with injudicious use of certain vitamins and minerals. Urge patients to follow specific dosage instructions. Keep out of reach of children. *Drug and Treatment Interactions:* As little as 5 mg pyridoxine daily can decrease the efficacy of levodopa in the treatment of parkinsonism. Not recommended for patients undergoing such therapy.
Adverse Reactions: Adverse reactions have been reported with specific vitamins and

ROCHE

,000,000 hospital
atients with
nfections.[4] Many are ano-
ic and may have a markedly
duced food intake. Supplements
e often provided as a prudent
easure because the vitamin sta-
s of critically ill patients cannot
readily determined.[5]

The incalculable millions on calorie-reduced diets. Patients ingesting 1000 or fewer calories per day could be at high risk because this intake may not supply most nutrients in adequate amounts without supplementation.[5]

als that generally at levels substan-
higher than those in Berocca Plus
(Vitamin E, allergic and idiosyncratic reac-
tions possible at lower levels than
at the usual recommended levels;
nausea associated with gastrointestinal
distress in some patients.

ge and Administration: Usual adult
dosage, one tablet daily. Not recom-
mended for children. Available on pre-
scription only.

Supplied: Golden yellow, capsule-
shaped tablets in bottles of 100.

HE LABORATORIES
ion of Hoffmann-La Roche Inc.
, New Jersey 07110

Berocca Plus
A balanced formula for prophylactic or therapeutic nutritional supplementation.

Berocca Plus Tablets provide: therapeutic levels of ascorbic acid and B-complex vitamins; supplemental levels of biotin, vitamins A and E, and five important minerals (iron, chromium, manganese, copper and zinc); plus magnesium. Berocca Plus is not intended for the treatment of specific vitamin and or mineral deficiencies.

Berocca Plus,
highly acceptable to patients, has virtually no odor or aftertaste and is economical. And its "Rx only" status means more physician involvement, better patient compliance.

References: 1. Shaw S, Lieber CS: Nutrition and alcoholism, chap. 40, in *Modern Nutrition in Health and Disease*, edited by Goodhart RS, Shils ME. Philadelphia, Lea & Febiger, 1980, pp. 1220, 1237. 2. Watkin DM: Nutrition for the aging and the aged, chap. 28, in *Modern Nutrition in Health and Disease*, *op. cit.*, p. 758. 3. Shils ME, Randall HT: Diet and nutrition in the care of the surgical patient, chap. 36, in *Modern Nutrition in Health and Disease*, *op. cit.*, pp. 1084, 1089, 1114. 4. Dixon RF: *Ann Intern Med* 89 (Part 2): 749-753, Nov. 1978. 5. Committee on Dietary Allowances, National Research Council: Recommended Dietary Allowances, ed 9, Washington, National Academy of Sciences, 1980, p. 13.

candidates for

Rx ONLY **Berocca® Plus** TABLETS

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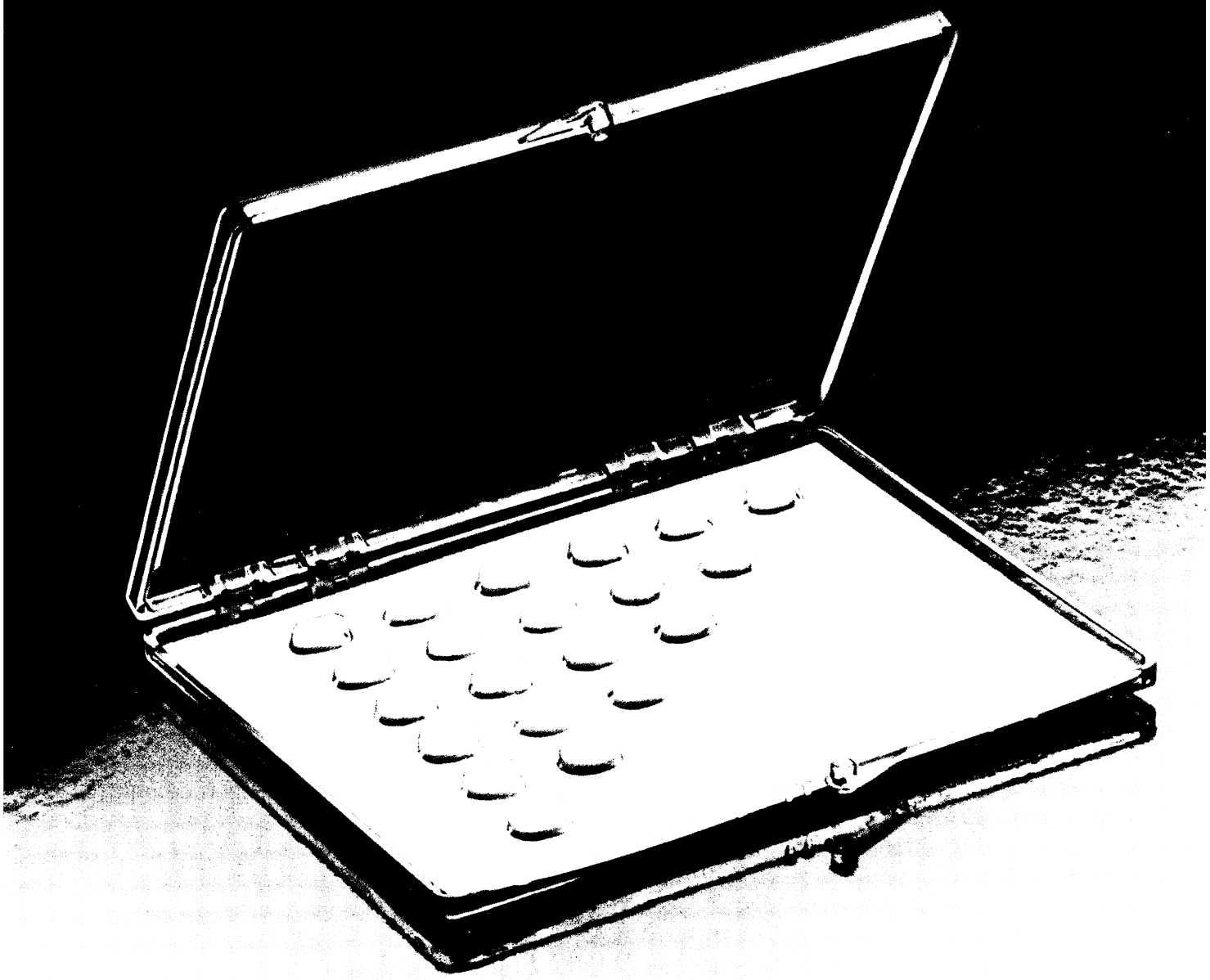
Upjohn

The Upjohn Company, Kalamazoo, Michigan 49001

Medrol® Dosepak™ Unit-of-Use

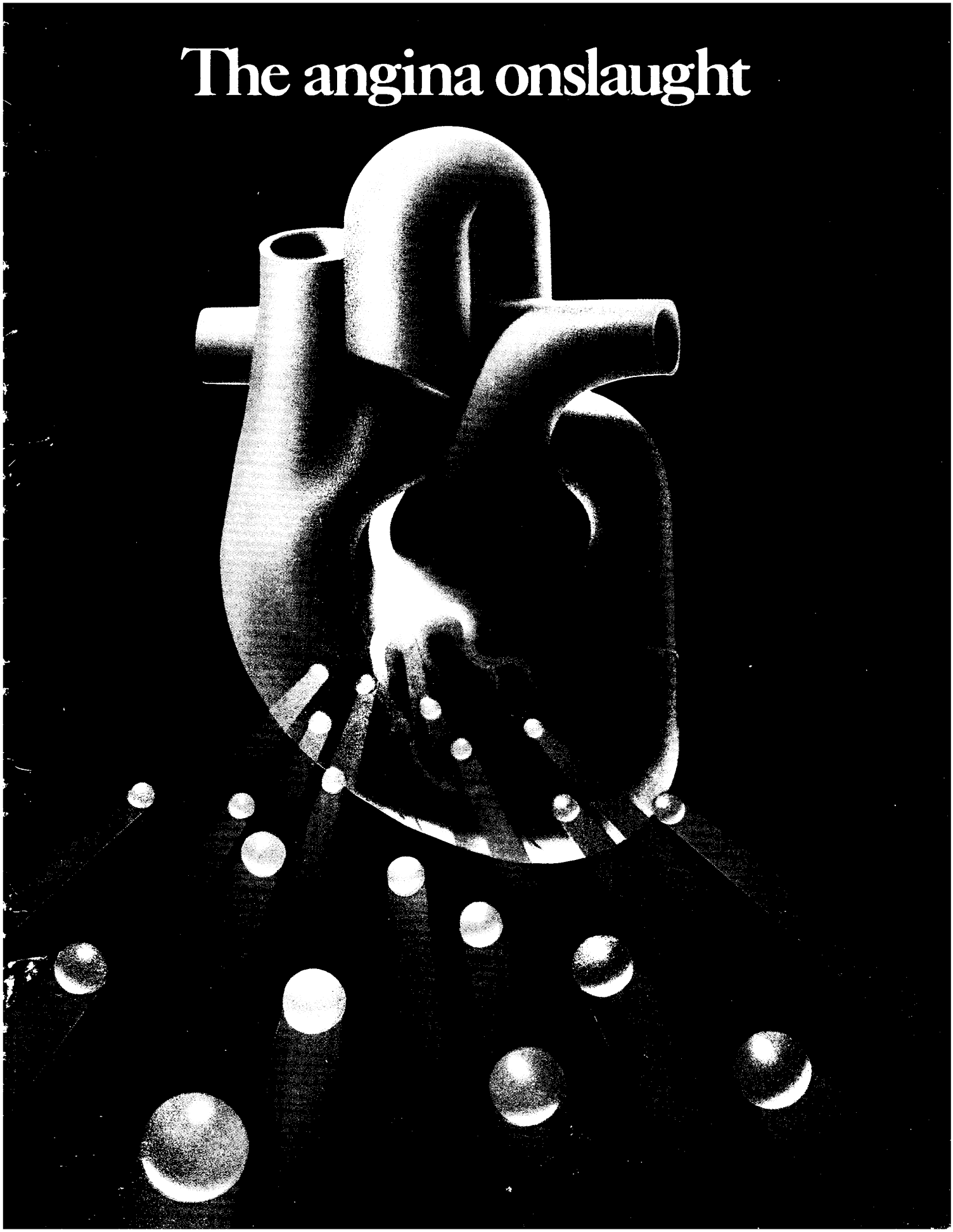
4 mg methylprednisolone tablets, USP

The explicit printed dosage instructions that accompany each *Dosepak* make it easy for the patient to understand and follow the dosage regimen.

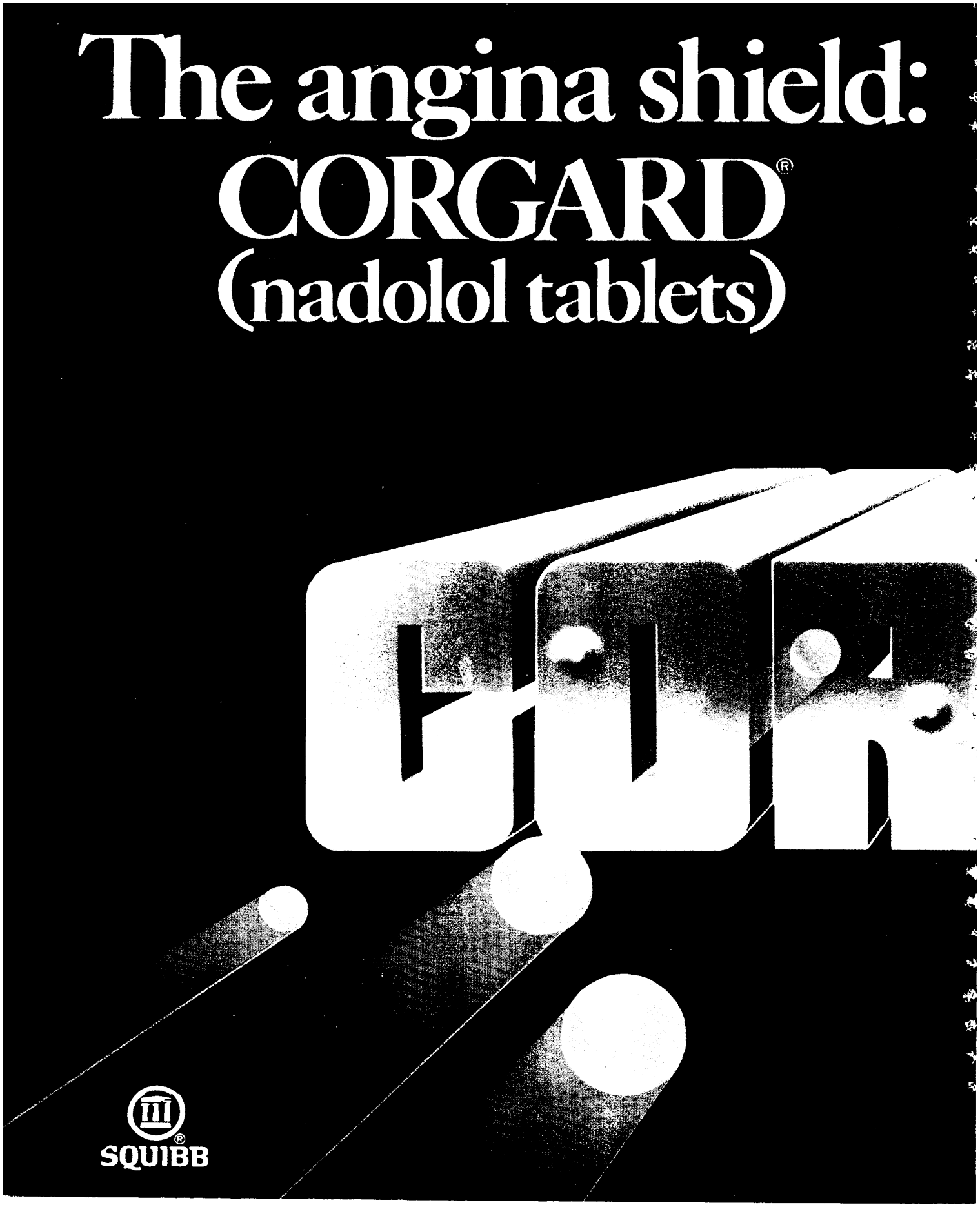


J-9305

The angina onslaught



The angina shield: CORGARD® (nadolol tablets)



SQUIBB®

Reliable 24-hour-a-day protection...

Physical exertion, emotional strain, and the unexpected crises of daily life — these can unleash an anginal attack at any time. So it's important to be certain that your patients are protected continuously. Unlike other beta-blockers, Corgard provides this protection around the clock with a once-daily dose — reducing the anginal attack rate, increasing work capacity, and decreasing the dependence on nitroglycerin.

with convenient once-a-day dosage

A single daily dose of Corgard controls angina all day, every day. And since Corgard is associated with a low incidence of side effects,* your patients can lead more comfortable lives. An added convenience of Corgard is that it can be taken at any time of day, regardless of meals, because its absorption is not affected by food.

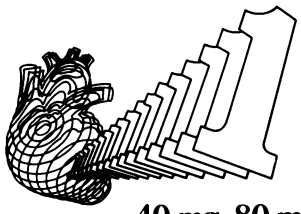
*For a full discussion of CONTRAINDICATIONS, PRECAUTIONS, ADVERSE REACTIONS, and WARNINGS, including avoidance of abrupt withdrawal, please see brief summary on next page.

CORGARD®
(nadolol tablets)

The only once-a-day beta-blocker for both angina pectoris and hypertension

Please see next page for brief summary.

The only once-a-day beta-blocker for both angina pectoris and hypertension



CORGARD® (nadolol tablets)

40 mg, 80 mg, 120 mg, and 160 mg scored tablets available in a variety of bottle sizes and in Convenience Packages of 40 mg and 80 mg tablets

CORGARD® TABLETS
Nadolol Tablets

DESCRIPTION: Corgard (nadolol) is a synthetic nonselective beta-adrenergic receptor blocking agent.

CONTRAINDICATIONS: Bronchial asthma, sinus bradycardia and greater than first degree conduction block, cardiogenic shock, and overt cardiac failure (see WARNINGS).

WARNINGS: Cardiac Failure — Sympathetic stimulation may be a vital component supporting circulatory function in congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of failure who are well-compensated, usually with digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure; therefore, at first sign or symptom of heart failure, digitalize and/or give diuretics, and closely observe response, or discontinue nadolol (gradually if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal — Hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after *abrupt* discontinuation of such therapy. When discontinuing chronic use of nadolol, particularly in patients with ischemic heart disease, gradually reduce dosage over a 1- to 2-week period and carefully monitor the patient. Reinstitute nadolol promptly (at least temporarily) and take other measures appropriate for management of unstable angina if angina markedly worsens or acute coronary insufficiency develops. Warn patients not to interrupt or discontinue therapy without physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue nadolol therapy abruptly even in patients treated only for hypertension.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolol with caution since it may block bronchodilation produced by endogenous or exogenous catecholamine stimulation of $beta_2$ receptors.

Major Surgery — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase risks of general anesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, it has generally been suggested that such therapy should be withdrawn several days prior to surgery. Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place. In emergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as isoproterenol, dopamine, dobutamine, or levarterenol can reverse the effects of nadolol. Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic receptor blocking agents.

Diabetes and Hypoglycemia — Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (e.g., tachycardia and blood pressure changes) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces release of insulin in response to hyperglycemia; therefore, it may be necessary to adjust dose of antidiabetic drugs.

Thyrotoxicosis — Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. To avoid abrupt withdrawal of beta-adrenergic blockade which might precipitate a thyroid storm, carefully manage patients suspected of developing thyrotoxicosis.

PRECAUTIONS: Impaired Hepatic or Renal Function — Use nadolol with caution in presence of either of these conditions (see DOSAGE AND ADMINISTRATION section of package insert).

Information for Patients — Warn patients, especially those with evidence of coronary artery insufficiency, against interruption or discontinuation of nadolol without physician's advice. Although cardiac failure rarely occurs in properly selected patients, advise patients being treated with beta-adrenergic blocking agents to consult physician at first sign or symptom of impending failure.

Drug Interactions — Catecholamine-depleting drugs (e.g., reserpine) may have an additive effect when given with beta-blocking agents. When treating patients with nadolol plus a catecholamine-depleting agent, carefully observe for evidence of hypotension and/or excessive bradycardia which may produce vertigo, syncope, or postural hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility — In 1 to 2 years' oral toxicologic studies in mice, rats, and dogs, nadolol did not produce significant toxic effects. In 2-year oral carcinogenic studies in rats and mice, nadolol did not produce neoplastic, preneoplastic, or nonneoplastic pathologic lesions.

Pregnancy — In animal reproduction studies with nadolol, evidence of embryo- and fetotoxicity was found in rabbits (but not in rats or hamsters) at doses 5 to 10 times greater (on a mg/kg basis) than maximum indicated human dose; no teratogenic potential was seen in any of these species. There are no well-controlled studies in pregnant women; therefore, use nadolol in pregnant women only if potential benefit justifies potential risk to the fetus.

Nursing Mothers — It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when nadolol is administered to a nursing woman. Animal studies showed that nadolol is found in the milk of lactating rats.

Pediatric Use — Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Most adverse effects have been mild and transient and have rarely required nadolol withdrawal.

Cardiovascular — Bradycardia with heart rates of less than 60 beats per minute occurs commonly, and heart rates below 40 beats per minute and/or symptomatic bradycardia were seen in about 2 of 100 patients. Symptoms of peripheral vascular insufficiency, usually of the Raynaud type, have occurred in approximately 2 of 100 patients. Cardiac failure, hypotension, and rhythm/conduction disturbances have each occurred in about 1 of 100 patients. Single instances of first degree and third degree heart block have been reported; intensification of AV block is a known effect of beta-blockers (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS). **Central Nervous System** — Dizziness or fatigue reported in approximately 2 of 100 patients; paresthesias, sedation, and change in behavior reported in approximately 6 of 1000 patients. **Respiratory** — Bronchospasm reported in approximately 1 of 1000 patients (see CONTRAINDICATIONS and WARNINGS). **Gastrointestinal** — Nausea, diarrhea, abdominal discomfort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. **Miscellaneous** — Each of the following reported in 1 to 5 of 1000 patients: rash; pruritus; headache; dry mouth, eyes, or skin; impotence or decreased libido; facial swelling; weight gain; slurred speech; cough; nasal stuffiness; sweating; tinnitus; blurred vision. Although relationship to drug usage is not clear, sleep disturbances have been reported. The oculomucocutaneous syndrome associated with practolol has not been reported with nadolol.

Potential Adverse Effects: Although other adverse effects reported with other beta-adrenergic blocking agents have not been reported with nadolol, they should be considered potential adverse effects of nadolol. **Central Nervous System** — reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place; short-term memory loss, emotional lability with slightly clouded sensorium; decreased performance on neuropsychometrics. **Gastrointestinal** — mesenteric arterial thrombosis; ischemic colitis. **Hematologic** — agranulocytosis; thrombocytopenic or nonthrombocytopenic purpura. **Allergic** — fever combined with aching and sore throat; laryngospasm; respiratory distress. **Miscellaneous** — reversible alopecia; Peyronie's disease; erythematous rash.

OVERDOSAGE: Nadolol can be removed from the general circulation by hemodialysis. In addition to gastric lavage, employ the following measures as appropriate. In determining duration of corrective therapy, take note of long duration of effect of nadolol.

Excessive Bradycardia — Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.

Cardiac Failure — Administer a digitalis glycoside and diuretic. It has been reported that glucagon may also be useful in this situation.

Hypotension — Administer vasopressors, e.g., epinephrine or levarterenol. (There is evidence that epinephrine may be the drug of choice.)

Bronchospasm — Administer a $beta_2$-stimulating agent and/or a theophylline derivative.

DOSAGE: For all patients, DOSAGE MUST BE INDIVIDUALIZED.

For **angina pectoris,** usual initial dose is 40 mg q.d.; gradually increase in 40 to 80 mg increments at 3 to 7 day intervals until optimum clinical response or pronounced slowing of the heart rate; usual maintenance dose is 80 to 240 mg q.d. (most patients respond to 160 mg or less daily). If treatment is to be discontinued, reduce dosage gradually over a period of 1 to 2 weeks (see WARNINGS).

For **hypertension,** usual initial dose is 40 mg q.d.; gradually increase in 40 to 80 mg increments until optimum blood pressure reduction is achieved; usual maintenance dose is 80 to 320 mg q.d. (rarely, doses up to 640 mg may be needed).

Patients with renal failure require adjustment in dosing interval; see package insert for dosage in these patients.

For full prescribing information, consult package insert.

HOW SUPPLIED: In scored tablets containing 40, 80, 120, or 160 mg nadolol per tablet in bottles of 100 and 1000 tablets and in Unimatic® unit-dose packs of 100 tablets. The 40 mg and 80 mg tablets are also available in convenience packages containing 4 blister cards of 7 tablets each.

SQUIBB®

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RUFEN®

(ibuprofen)

measures up... at a reasonable cost!

Far-Reaching Effectiveness for Arthritis Patients

Rufen® offers your patient effective relief, both as first therapy or after other potent medications fail. In comparable trials with indomethacin[1,2] sulindac,[3,4] and other antiarthritic agents,[5-7] findings consistently demonstrate high improvement with ibuprofen (Rufen) by such objective and subjective measures as reduction of swelling, improved grip strength,[1] reduced morning stiffness,[1] better ambulation,[2] improved range of motion,[4] reduction and relief of pain.[1-5]

Low Score in Side-Effect Risk

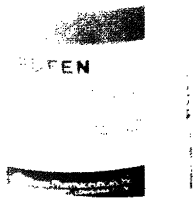
Through more than 13 years of worldwide use, ibuprofen continues to demonstrate exceptional gastrointestinal tolerance vis-a-vis aspirin and other antiarthritic agents. In a recent series of double-blind trials of ibuprofen, naproxen and other NSAID's, only placebo was shown to produce less G.I. lesions than ibuprofen on gastroscopic examination.[5]

Boots Pharmaceuticals, Inc.
Shreveport, LA 71106
Pioneers in medicine for the family

See next page for brief summary of prescribing information.

Measure
RUFEN®
(ibuprofen)
for GI Tolerance

Even in arthritic patients with a history of GI disease



And Rufen® Measures Up Best

Over a five-year period, ibuprofen was administered to 61 patients with known peptic ulceration and 42 with known gastric intolerance to other antiarthritis drugs.

Twenty-six patients remained in treatment, 23 left treatment following remission, and 35 dropped out for reasons unrelated to side effects. In this specially selected group of GI-intolerant patients, only 13 (12.3%) discontinued ibuprofen because of GI intolerance.

"Any drug used in the control of the symptoms of the chronic arthritis must be tolerated for long periods without undue gastric discomfort...From this study it appears that ibuprofen is eminently suitable."[7]

Peptic ulceration and GI bleeding, sometimes severe, have been reported. Rufen® should be given under close supervision to patients with a history of upper GI tract disease.

References: 1. Royer GL, Jr, Moxley TE, Hearron MS, et al: *J Int Med Res* 3:158-171, 1975. 2. Royer GL, Jr, Moxley TE, Hearron MS, et al: *Curr Therap Res* 17:235-248, 1975. 3. Brackertz B, Bussow M: *Brit J Clin Pract* 32:77-80, 1978. 4. Rausch J, Fasching U: *Brit J Clin Pract: A symposium supplement, IXTH European Congress of Rheumatology*, Wiesbaden, Germany, Sept 2-8, 1979, pp 65-6. 5. Lanza FL, Royer GL, Jr, Nelson RS et al: *Dig Dis & Sci* 24:578-585, 1979. 6. Pavelka K, Susta A, Vojtisek A et al: *Rheumatol int Rehab* 2:265-70, 1982. 7. Trevelyan W: *Brit J Clin Pract: A symposium supplement, IXTH European Congress of Rheumatology*, Wiesbaden, Germany, Sept 2-8, 1979, pp 55-62. 8. Cardoe N: *Curr Med Res & Opinion* 5:548-550, 1978.

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Shreveport, LA 71106
Pioneers in medicine for the family

RUFEN® (ibuprofen) Tablets

INDICATIONS AND USAGE:

Relief of mild to moderate pain. Treatment of primary dysmenorrhea

CONTRAINDICATIONS:

WARNINGS:

PRECAUTIONS:

DRUG INTERACTION:

PREGNANCY AND NURSING MOTHERS:

ADVERSE REACTIONS: Incidence greater than 1%. Gastrointestinal:

Incidence less than 1 in 100. Gastrointestinal:

Causal relationship unknown. Gastrointestinal:

OVERDOSAGE:

DOSAGE AND ADMINISTRATION:

Dysmenorrhea

CAUTION:

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Today, INDERAL—instead of methyldopa, instead of reserpine.

INDERAL exhibits few of the disturbing side effects of methyldopa and reserpine. Sedation, depression, and impotence are rare.* Tolerance is not likely to occur, as it frequently does with methyldopa. For the vast majority of patients—INDERAL means a step toward improving the quality of life. (INDERAL should not be used in the presence of congestive heart failure, sinus bradycardia, heart block greater than first degree, and bronchial asthma.)*

INDERAL blocks beta-receptor sites *in the heart* to reduce heart rate and cardiac output—reducing cardiac work load—sparing an overburdened heart.

Hypertensive hearts can rest easy with INDERAL. For many—it is ideal, first-step therapy.

INDERAL—the sooner, the better for hypertension—a leading risk factor in coronary heart disease.[1]

INDERAL (propranolol HCl) B.I.D.

The sooner, the better.

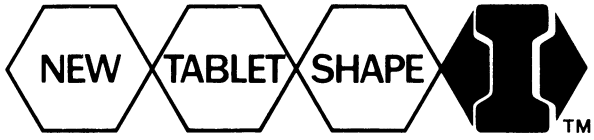
*Please see following page for Brief Summary of Prescribing Information.

THE MOST WIDELY PRESCRIBED BETA BLOCKER IN THE WORLD

INDERAL®

(PROPRANOLOL HCl)

B.I.D. FOR HYPERTENSION



The appearance of these tablets is a trademark of Ayerst Laboratories

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)
Inderal® (propranolol hydrochloride)

BEFORE USING INDERAL (PROPRANOLOL HYDROCHLORIDE), THE PHYSICIAN SHOULD BE THOROUGHLY FAMILIAR WITH THE BASIC CONCEPT OF ADRENERGIC RECEPTORS (ALPHA AND BETA), AND THE PHARMACOLOGY OF THIS DRUG.

CONTRAINDICATIONS

1) bronchial asthma; 2) allergic rhinitis during the pollen season; 3) sinus bradycardia and greater than first degree block; 4) cardiogenic shock; 5) right ventricular failure secondary to pulmonary hypertension; 6) congestive heart failure (see WARNINGS) unless it is secondary to a tachyarrhythmia treatable with propranolol; 7) in patients on adrenergic-augmenting psychotropic drugs (including MAO inhibitors), and during the two week withdrawal period from such drugs.

WARNINGS

CARDIAC FAILURE. In congestive heart failure, inhibition with beta-blockade carries the potential hazard of further depressing myocardial contractility and precipitating cardiac failure. In patients already receiving digitalis, propranolol may reduce the positive inotropic action of digitalis and may have an additive depressant effect on AV conduction.

IN PATIENTS WITHOUT A HISTORY OF CARDIAC FAILURE, in rare instances, cardiac failure has developed during propranolol therapy. At the first sign of impending cardiac failure, patients should be fully digitalized and/or given a diuretic, and observed closely. a) if cardiac failure continues, despite adequate digitalization and diuretic therapy, propranolol should be immediately withdrawn; b) if tachyarrhythmia is being controlled, patients should be maintained on combined therapy and closely followed until threat of cardiac failure is over.

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following *abrupt* discontinuation of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned the dosage should be gradually reduced and the patient carefully monitored. In addition, when INDERAL is prescribed for angina pectoris, the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease, who are given propranolol for other indications.

IN PATIENTS WITH THYROTOXICOSIS, possible deleterious effects from long term use have not been adequately appraised. Give special consideration to propranolol's potential for aggravating congestive heart failure. Propranolol may mask the clinical signs of developing or continuing hyperthyroidism or complications and give a false impression of improvement. Propranolol should be withdrawn slowly, since abrupt withdrawal may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

IN PATIENTS UNDERGOING MAJOR SURGERY, beta-blockade impairs the ability of the heart to respond to reflex stimuli. Except in pheochromocytoma, propranolol should be withdrawn 48 hours prior to surgery. In case of emergency surgery, the effects of propranolol can be reversed by administration of beta-receptor agonists such as isoproterenol or levarterenol, but such patients may be subject to protracted severe hypotension. Difficulty in restarting and maintaining the heart beat has been reported.

IN PATIENTS PRONE TO NONALLERGIC BRONCHOSPASM (*e.g.*, CHRONIC BRONCHITIS, EMPHYSEMA), administer with caution, since propranolol may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta-receptors.

DIABETICS AND PATIENTS SUBJECT TO HYPOGLYCEMIA: Propranolol may prevent the appearance of premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia, especially in patients with labile diabetes. A precipitous elevation of blood pressure may accompany hypoglycemic attacks.

USE IN PREGNANCY: Safe use in human pregnancy not established. Embryotoxic effects have been seen in animals at doses about 10 times the maximum recommended human dose.

PRECAUTIONS

Patients receiving catecholamine depleting drugs such as reserpine should be closely observed if propranolol is administered, since it may occasionally produce hypotension and/or marked bradycardia resulting in vertigo, syncopal attacks, or orthostatic hypotension.

Observe laboratory parameters at regular intervals. Use with caution in patients with impaired renal or hepatic function.

ADVERSE REACTIONS

Cardiovascular: bradycardia; congestive heart failure; intensification of AV block; hypotension; paresthesia of hands; arterial insufficiency, usually of the Raynaud type; thrombocytopenic purpura. *Central Nervous System*: lightheadedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. *Gastrointestinal*: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation; mesenteric arterial thrombosis; ischemic colitis. *Allergic*: pharyngitis and agranulocytosis; erythematous rash; fever combined with aching and sore throat; laryngospasm and respiratory distress. *Respiratory*: bronchospasm. *Hematologic*: agranulocytosis; nonthrombocytopenic purpura; thrombocytopenic purpura. *Miscellaneous*: reversible alopecia. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta-blocker (practolol) have not been conclusively associated with propranolol. *Clinical Laboratory Test Findings*: Elevated blood urea levels in patients with severe heart disease; elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

HOW SUPPLIED

TABLETS

—Each hexagonal-shaped, orange, scored tablet is embossed with an "I" and imprinted with "INDERAL 10," contains 10 mg propranolol hydrochloride, in bottles of 100 (NDC 0046-0421-81) and 1,000 (NDC 0046-0421-91). Also in unit dose package of 100 (NDC 0046-0421-99).

—Each hexagonal-shaped, blue, scored tablet is embossed with an "I" and imprinted with "INDERAL 20," contains 20 mg propranolol hydrochloride, in bottles of 100 (NDC 0046-0422-81) and 1,000 (NDC 0046-0422-91). Also in unit dose package of 100 (NDC 0046-0422-99).

—Each hexagonal-shaped, green, scored tablet is embossed with an "I" and imprinted with "INDERAL 40," contains 40 mg propranolol hydrochloride, in bottles of 100 (NDC 0046-0424-81) and 1,000 (NDC 0046-0424-91). Also in unit dose package of 100 (NDC 0046-0424-99).

—Each hexagonal-shaped, yellow, scored tablet is embossed with an "I" and imprinted with "INDERAL 80," contains 80 mg propranolol hydrochloride, in bottles of 100 (NDC 0046-0428-81) and 1,000 (NDC 0046-0428-91). Also in unit dose package of 100 (NDC 0046-0428-99).

The appearance of these tablets is a trademark of Ayerst Laboratories.

Store at room temperature (approximately 25° C).

INJECTABLE

—Each ml contains 1 mg of propranolol hydrochloride in Water for Injection. The pH is adjusted with citric acid. Supplied as 1 ml ampuls in boxes of 10 (NDC 0046-3265-10).

Store at room temperature (approximately 25° C).

7997/882

Reference: 1. Freis, E. D.: Hypertension (Suppl. II) 3:230 (Nov.-Dec.) 1981.

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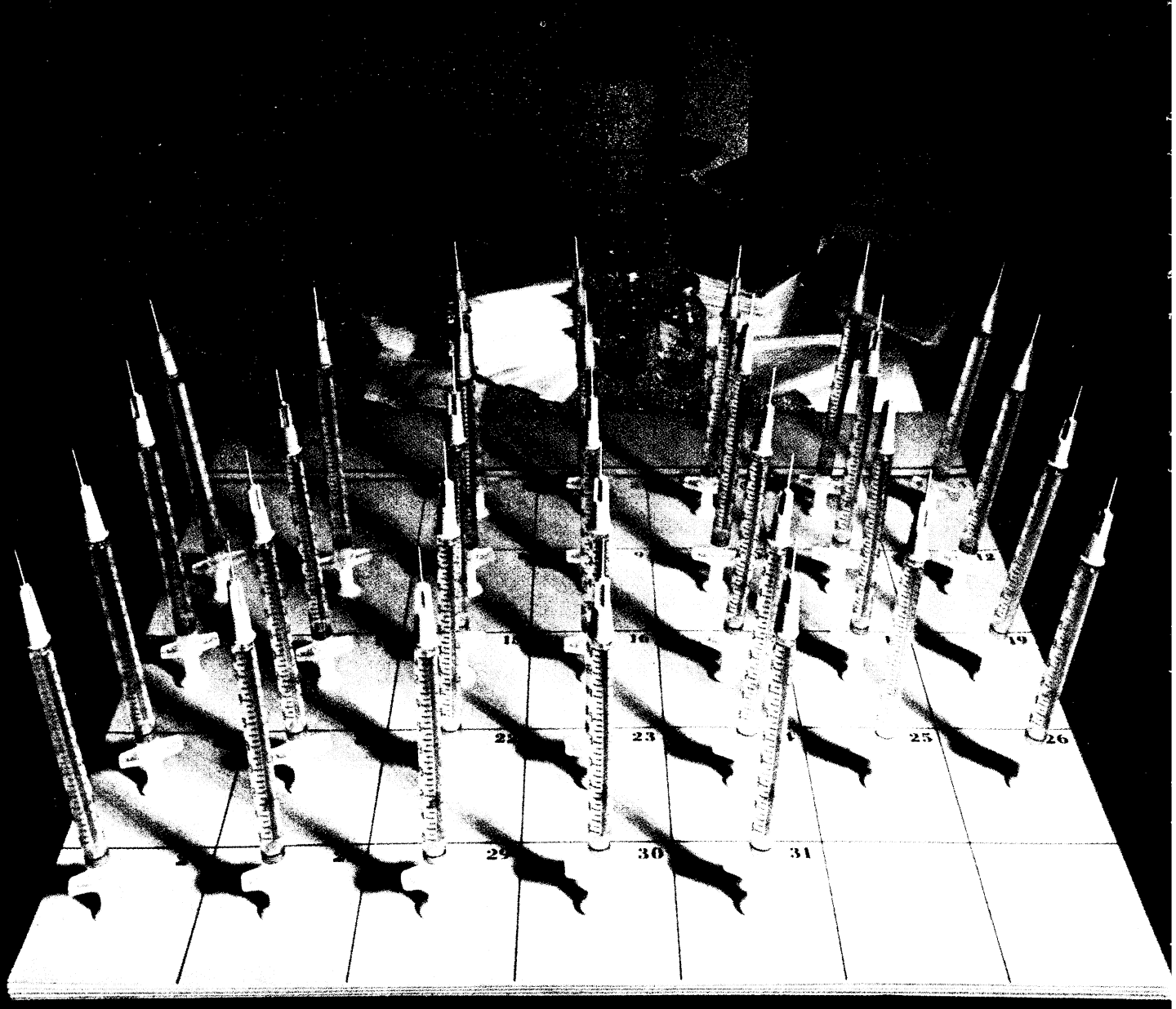

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As many as 80% of diabetics are non-insulin-dependent. The problem is not insulin insufficiency but insulin insensitivity at the cellular level.[1,2]

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Diabinese, the distinctive blue, D-shaped, chlorpropamide tablet from Pfizer, is the only oral hypoglycemic with once-a-day convenience, regardless of dosage. And it is economical.

*As with all sulfonylureas, hypoglycemia may occur, but less frequently than with insulin therapy.

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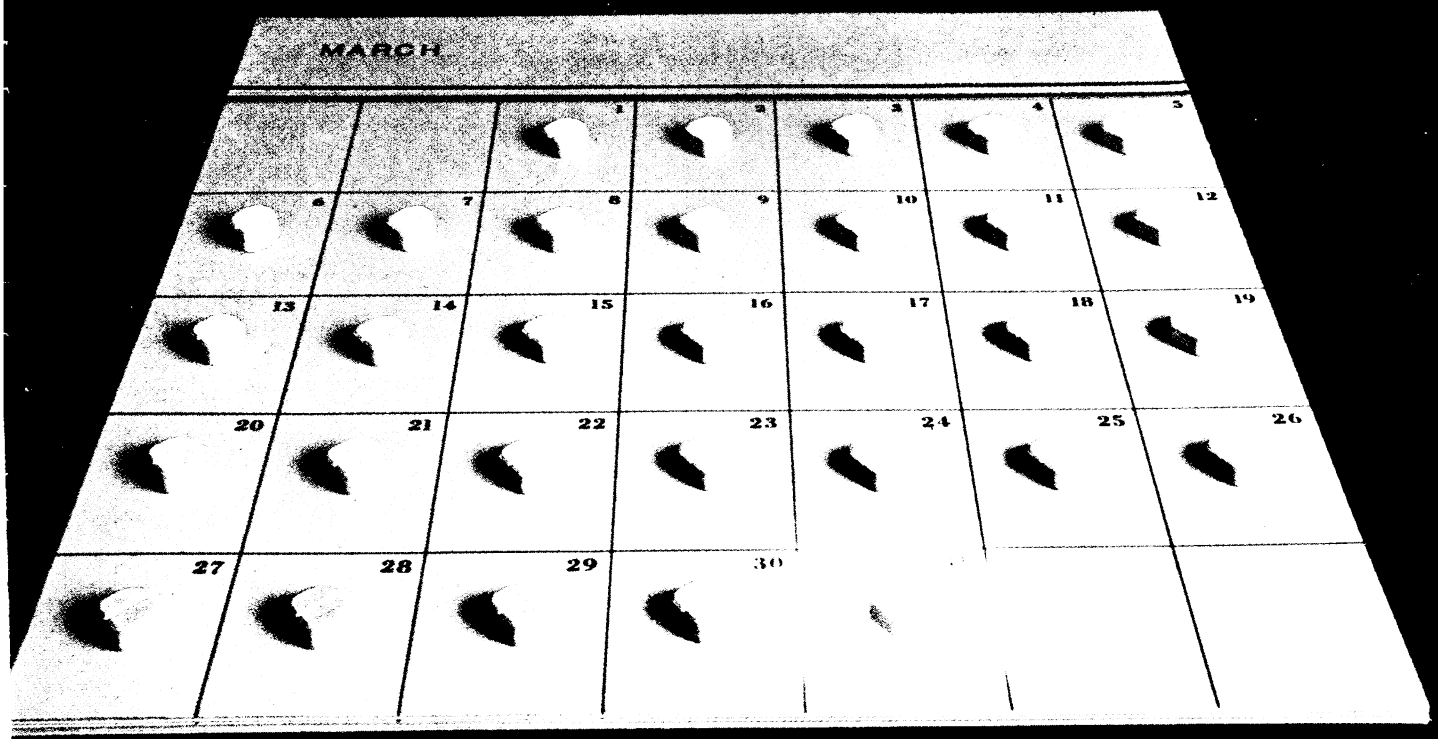

Diet & Diabinese® (chlorpropamide)

Tablets 100 mg and 250 mg

A proven regimen for effective control of blood sugar.

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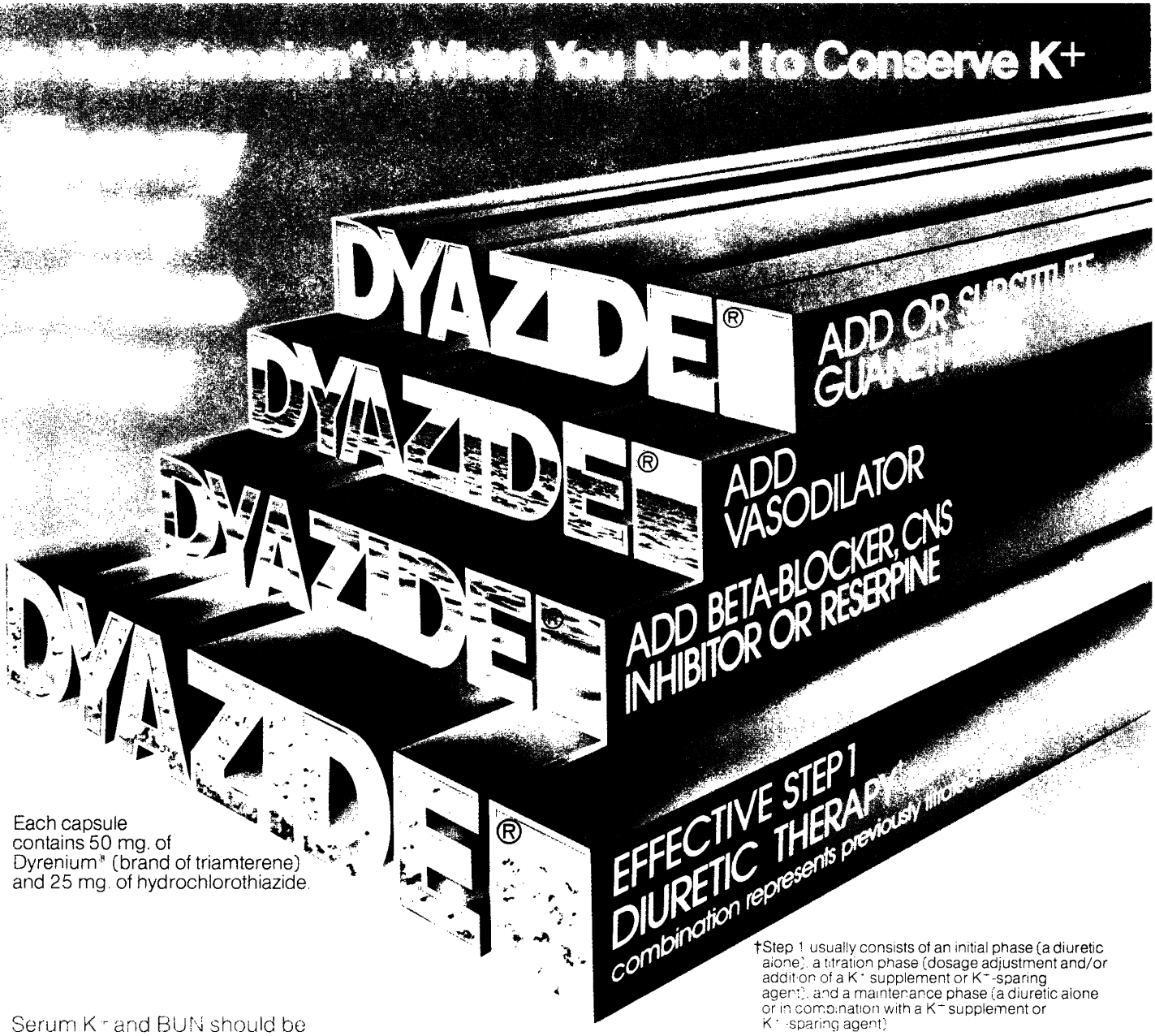
Replacement . . . When You Need to Conserve K+



Each capsule contains 50 mg. of Dyrenium® (brand of triamterene) and 25 mg. of hydrochlorothiazide.

†Step 1 usually consists of an initial phase (a diuretic alone), a titration phase (dosage adjustment and/or addition of a K^+ supplement or K^+-sparing agent), and a maintenance phase (a diuretic alone or in combination with a K^+ supplement or K^+-sparing agent).

Serum K^+ and BUN should be checked periodically (see Warnings).

Before prescribing, see complete prescribing information in SK&F CO. literature or *PDR*. The following is a brief summary.

★ **WARNING**

[redacted]

Contraindications: [redacted]

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. [redacted]

Associated widened QRS complex or arrhythmia requires prompt additional therapy. [redacted]

[redacted]

[redacted] which rarely has been reported with triamterene/hydrochlorothiazide therapy.

Precautions: Do periodic serum electrolyte determinations [redacted] particularly important in patients vomiting excessively or receiving parenteral fluids and during concurrent use with antineoplastic B or corticosteroids or corticotropin (ACTH). Periodic BUN and serum creatinine determinations should be made especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Triamterene should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with triazides. Triazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responses to pressor agents, such as norepinephrine, have been reported. Triazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, Dyazide should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on Dyazide when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with Dyazide. The following may result in transient elevated BUN or creatinine or both: hyperglycemia and glycosuria, diabetic insulin requirements may be altered, hyperuricemia and gout or gouty arthritis may be precipitated, decreased alkali reserve with possible mild transient acidosis. Dyazide interferes with fluorescent measurement of quinine. Hyponatremia is uncommon with Dyazide but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and Dyazide should abnormal values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by triazides. Dyazide should be withdrawn before conducting tests for parathyroid function.

Triazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, uterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis and vertigo have occurred with triazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on Dyazide although a causal relationship has not been established.

Supplied: Bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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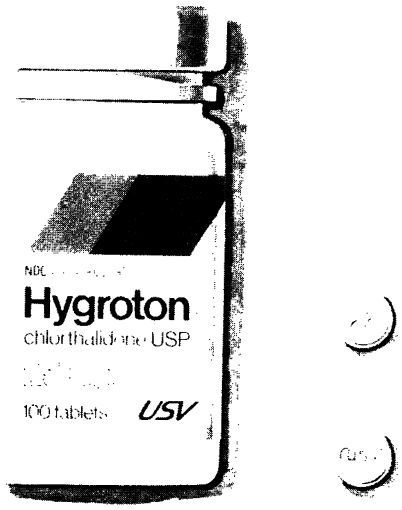

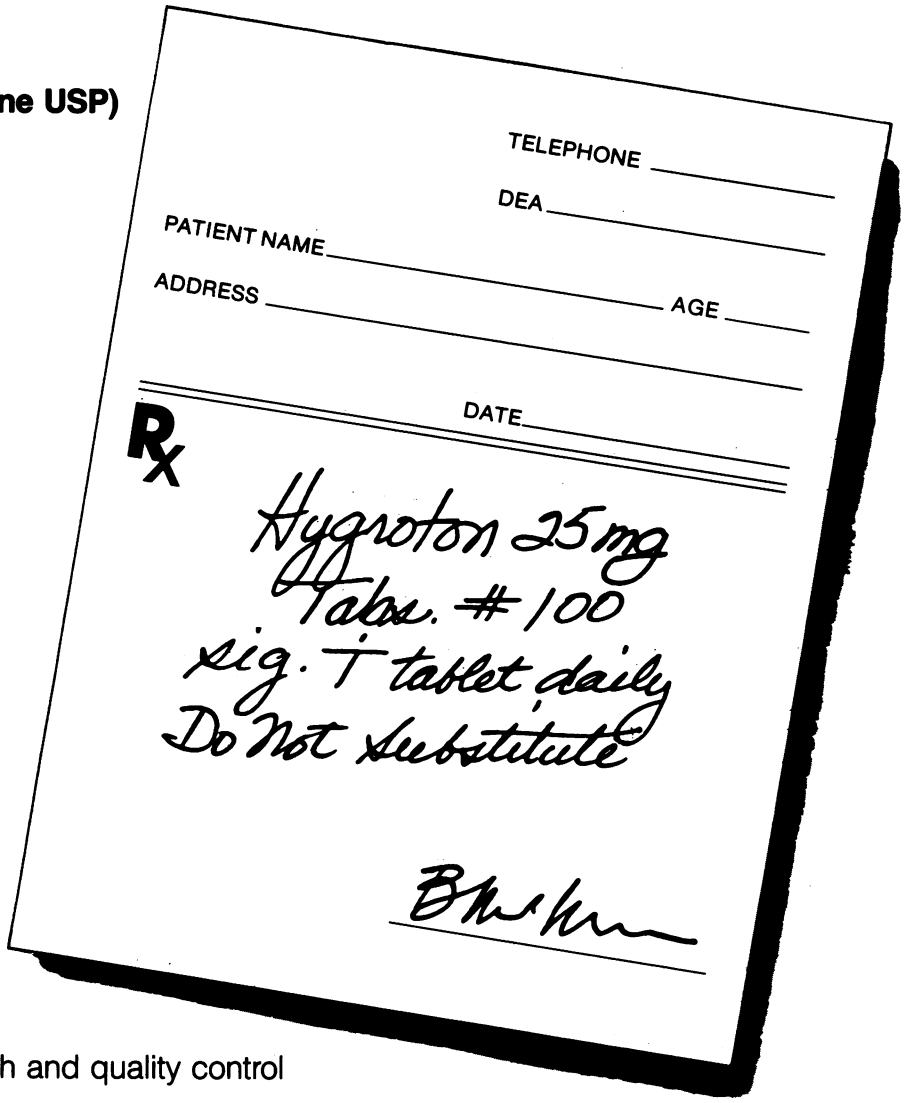

- Proven efficacy and safety
- Convenient once-daily dosage
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BRIEF SUMMARY

Indications: Hypertension, adjunctive therapy in edema.

Contraindications: Anuria, hypersensitivity to chlorthalidone or other sulfonamide-derived drugs.

Warnings: Should be used with caution in severe renal disease, impaired hepatic function or progressive liver disease. May add to or potentiate the action of other antihypertensive drugs. Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma. There is a possibility of exacerbation or activation of systemic lupus erythematosus with thiazides, which are related to chlorthalidone. This has not been reported with chlorthalidone. Thiazides cross the placental barrier and appear in cord blood. Use in pregnant women requires that the anticipated benefits of the drug be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult. In nursing mothers, thiazides cross the placental barrier and appear in breast milk. If use of the drug is essential, the patient should stop nursing.

Precautions: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving chlorthalidone should be observed for clinical signs of fluid or electrolyte imbalance; namely, hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Hypokalemia may develop with chlorthalidone as with any other potent diuretic, especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids or ACTH. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Digitalis therapy may exaggerate metabolic effects of hypokalemia especially with reference to myocardial activity. Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather. Hyperuricemia may occur or gout be precipitated in certain patients. Insulin requirements in diabetic patients may be increased, decreased, or unchanged and latent diabetes mellitus may become manifest. Chlorthalidone and related drugs may increase the responsiveness to tubocurarine. The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient. Chlorthalidone and related drugs may decrease arterial responsiveness to norepinephrine. If progressive renal impairment becomes evident, as indicated by a rising nonprotein nitrogen or blood urea nitrogen, a careful reappraisal of therapy is necessary with consideration given to withholding or discontinuing diuretic therapy. Chlorthalidone and related drugs may decrease serum PBI levels without signs of thyroid disturbance.

Adverse Reactions: Anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis; dizziness, vertigo, paresthesias, headache, xanthopsia; leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia; purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis) (cutaneous vasculitis), Lyell's syndrome (toxic epidermal necrolysis). Orthostatic hypotension may occur and may be aggravated by alcohol, barbiturates or narcotics. Other adverse reactions include hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restlessness, impotence. Whenever adverse reactions are moderate or severe, chlorthalidone dosage should be reduced or therapy withdrawn.

Usual Dose: One tablet daily.

How Supplied: Tablets—100 mg. (white, scored), 50 mg. (aqua) in bottles of 100, 1000 and 5000; 25 mg. (peach) in bottles of 100 and 1000; unit-dose blister packs, boxes of 100 (10 x 10 strips).

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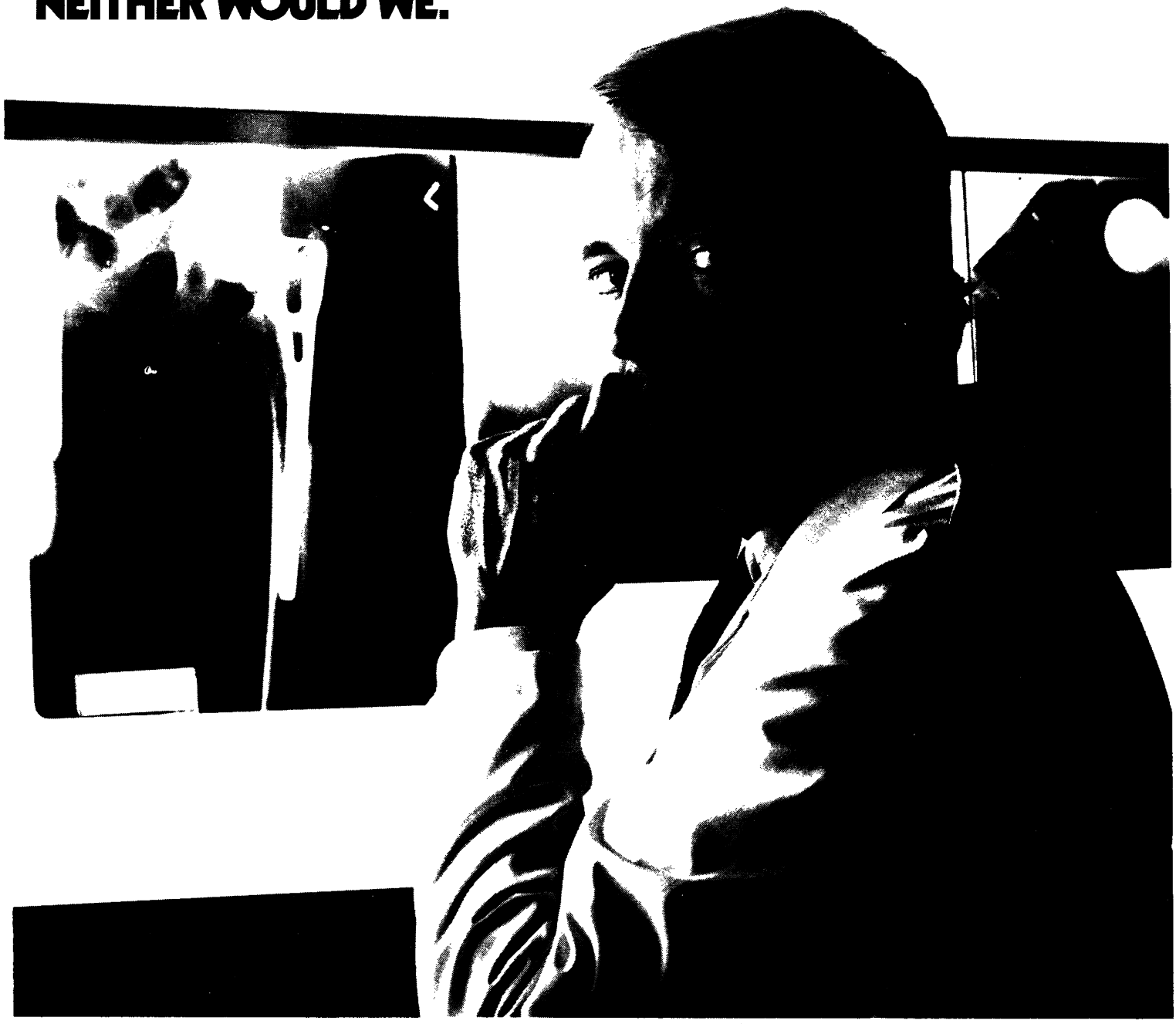

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ORTHOPEDIC SURGEON: Immediate opening for fully trained, Board Certified or eligible physician in a multi-specialty group. Attractive San Francisco Bay area. Send CV to Recruitment Committee, San Jose Medical Clinic, 45 South 17th St., San Jose, CA 95112.

SEEK BOARD ELIGIBLE OR CERTIFIED RADIOLOGIST to join long established private practice group, Los Angeles area. Ultrasound training required. Submit CV to Box 6340, Western Journal of Medicine, 731 Market St., San Francisco, CA 94103.

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FAMILY PRACTICE/INTERNIST, Powell, Wyoming. Two physicians for new clinic. Community of 5,300, 75 miles east of Yellowstone Park. Guarantees plus benefits. Contact Raymond Wolf, collect (414) 785-6500 or (414) 327-1797.

FAMILY PRACTICE PHYSICIANS needed for clinic in central Idaho. Mountain recreation area seeks full-time family practitioner for established practice with excellent facilities and organized specialty report. Guaranteed income with incentive. Excellent skiing, hiking and fishing. Write Box 6345, Western Journal of Medicine, 731 Market St., San Francisco, CA 94103.

ONCOLOGIST/HEMATOLOGIST to join group of medical oncologists. Clinical appointment at the University of Nevada School of Medicine. Active participation in the Southwest Oncology Group. For further details contact: Joseph M. Quagliana, MD, 3380 South Eastern Ave., Las Vegas, NV 89109. Telephone: (702) 733-6488.

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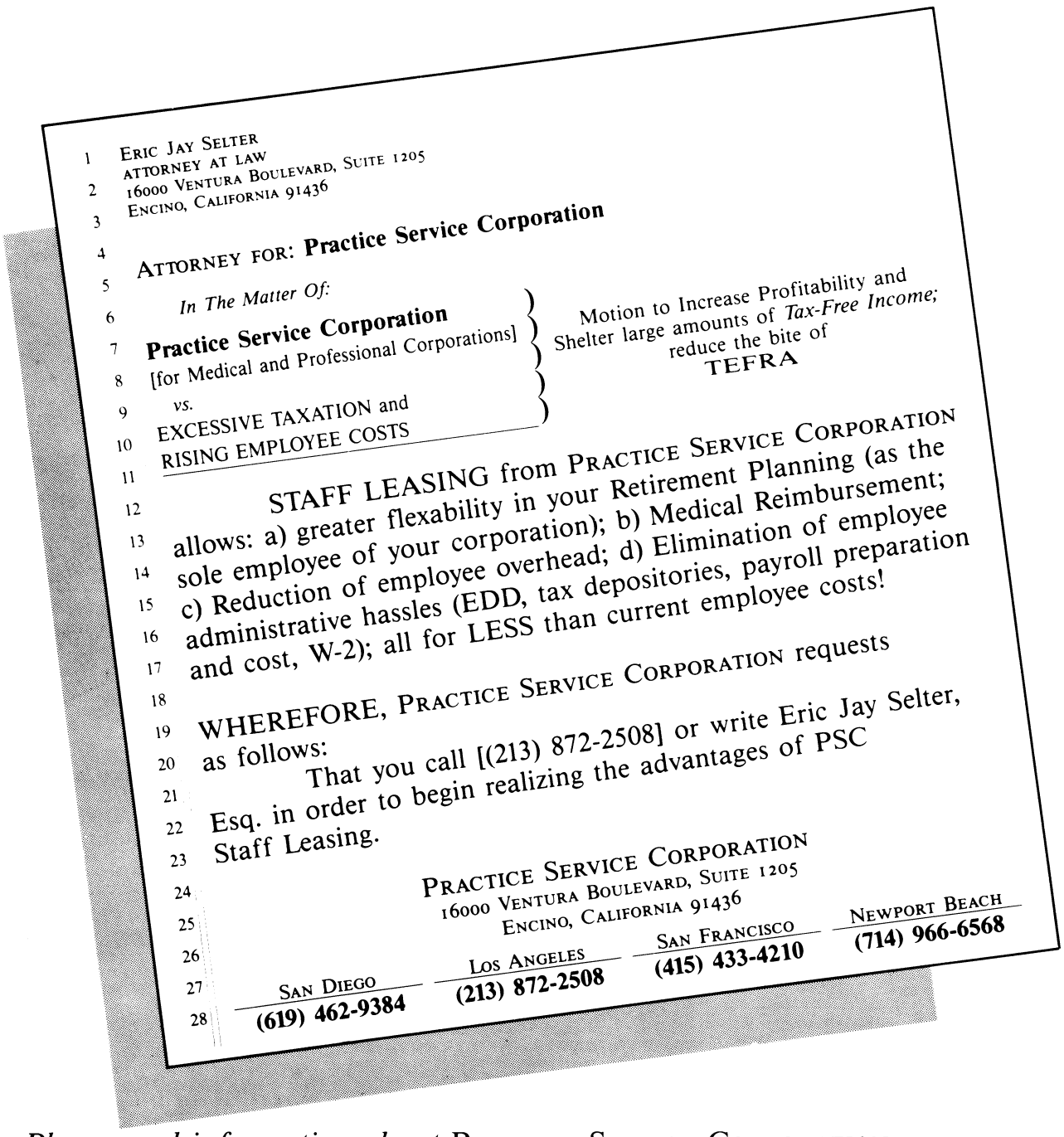
ORTHOPAEDIC SURGEON—Physician sought to join General Orthopaedic Practice in small town in Washington State on the Olympic Peninsula. All practice arrangements considered. Close to metropolitan areas, unlimited recreational opportunities. Superior office layout with x-ray; adjoining Physical Therapy/Sports Medicine Clinic. Located next to County Hospital. Attn: K. Look, 2300 Kati Court, Shelton, WA 98584. (206) 426-7914.

(Continued on Page 450)

PSC Staff Leasing *vs.* TEFRA



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(Continued from Page 448)

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(Continued on Page 452)

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$10,062.27	$1,056.54	$11,118.51
15,093.40	1,584.81	16,678.21
20,124.53	2,113.08	22,237.61
25,155.66	2,641.34	27,797.00

ANNUAL PERCENTAGE RATE: 21%
(Credit Life Insurance also available.)

TO APPLY:

(1) Complete and sign application below. If additional space is needed, please provide on additional sheet of paper.

(2) *Include a complete copy of your most current Federal Income Tax Return and mail to:*

SFC Financial Services
Mr. Charles M. Mathis, Jr.
Executive Vice President
50 S. Main St., Suite 460
Salt Lake City, Utah 84144
TOLL-FREE: 1-800-453-9494 COLLECT: 801-322-3422

SFC FEATURES

- ★ **UNSECURED**
- ★ **CONFIDENTIAL**
- ★ **CONVENIENT**
- ★ **PROMPT SERVICE**
  3-day loan approval, Finalized in 7-10 working days.
- ★ **FLEXIBLE REPAYMENT PLANS**
- ★ **PREPAYMENT ADVANTAGES**
- ★ **DEAL DIRECT-NO BROKER FEES:**
  No additional fees, points or service charges of any kind.
- ★ **EXCLUSIVE 6-MONTH SINGLE PAYMENT PLAN**

EXECUTIVE/PROFESSIONAL LOAN APPLICATION

I REQUEST AN IMMEDIATE LOAN OF $_____ NUMBER OF MONTHS _____ MONTHLY PAYMENT AMOUNTS $_____

PURPOSE OF LOAN _____

PERSONAL HISTORY

PRINT NAME (FIRST)	(MIDDLE)	(LAST)	DATE OF BIRTH
ADDRESS (HOME)			HOME PHONE/AREA CODE
CITY	STATE	ZIP CODE	YEARS ☐ RENT ☐ OWN
MORTGAGE HOLDER			YOUR SOCIAL SECURITY NO.
PROFESSION			
BUSINESS ADDRESS			BUSINESS PH. / AREA CODE
CITY	STATE	ZIP CODE	NET ANNUAL INCOME

FINANCIAL INFORMATION

*If any assets listed below are jointly owned with others or any other person has an interest in same, state name of co-owner, or co-party of interest, and % of interest by specific asset.

ASSETS		LIABILITIES	
REAL ESTATE (LIST ADDRESSES)	$	REAL ESTATE MORTGAGES (LIST FIRM & ADDRESS)	$
CASH & ACCTS. RECEIVABLE (LIST)		LOANS & ACCTS. PAYABLE (LIST)	
STOCKS AND BONDS (LIST)			
AUTOMOBILES (LIST)		BUSINESS EQUIPMENT & LEASES	
OTHER ASSETS (LIST)		OTHER DEBTS & ANY CONTINGENT LIABILITIES (LIST)	
TOTAL ASSETS	$	**TOTAL LIABILITIES**	$
		NET WORTH	$

THE UNDERSIGNED CERTIFIES THAT THE INFORMATION INSERTED HEREIN AND IN ANY ACCOMPANYING DOCUMENTS HAS BEEN CAREFULLY READ AND IS TRUE AND CORRECT AND IS GIVEN FOR THE PURPOSE OF INITIATING THE EXTENSION OF CREDIT THROUGH SFC FINANCIAL SERVICES TO THE UNDERSIGNED AND CONFIRMS THE INTENT OF THE UNDERSIGNED THAT THE CONSTRUCTION, VALIDITY AND EFFECT OF THE CREDIT EXTENDED AND ALL TRANSACTIONS AND ALL RIGHTS OF THE PARTIES PERTAINING THEREOF SHALL BE GOVERNED BY THE LAWS OF THE STATE OF UTAH.

Date Signed _____ **19** _____ **Signature** _____

(DETACH AND MAIL. INCLUDE ADDITIONAL MATERIAL REQUESTED IN ITEMS (1) AND (2) ABOVE.)
(Not applicable to residents of AR, NC, OR, WA, AK & HI. CA residents $10,000 minimum—personal, family or household loans only.) WJ3/83

A Policy of Extra-Low Dose Oral Contraception

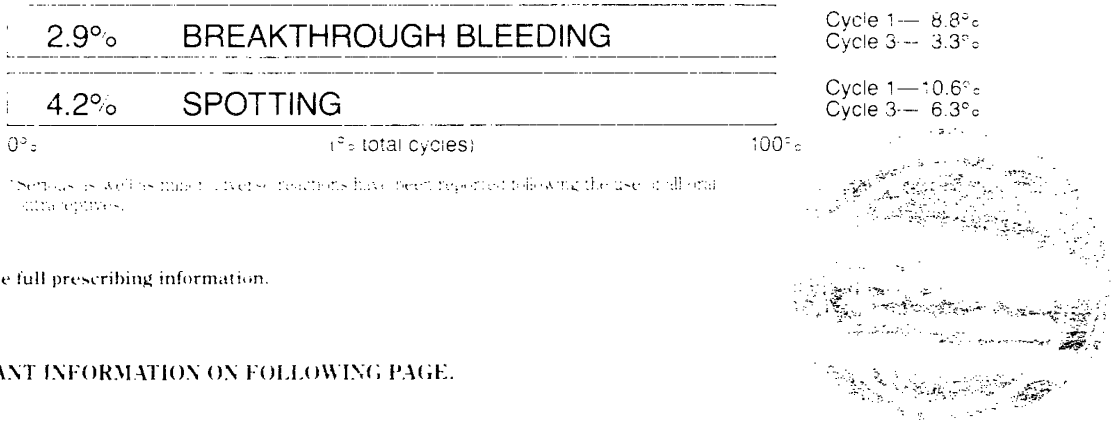
BENEFIT #1: EXTRA-LOW DOSE

The dosage is lower than "low." Lo Ovral contains an "extra-low" total hormone dose—30 mcg ethinyl estradiol and just 0.3 mg norgestrel. Even at this extra-low dose there was no reduction in contraceptive effectiveness. Nor any overall increase in breakthrough bleeding.*

BENEFIT #2: EARLY CYCLE BREAKTHROUGH PROTECTION

Lo Ovral offers your patients protection against breakthrough bleeding and spotting when they need it most—in the early cycles.* That's when they're usually most vulnerable to intermenstrual bleeding.

And in clinical trials totalling 22,489 cycles Lo Ovral achieved a near-spotless record.* Just look below.



*Spotting is defined as mild intermenstrual bleeding that does not require the use of additional sanitary protection.

See full prescribing information.

SEE IMPORTANT INFORMATION ON FOLLOWING PAGE.

EXTRA-LOW DOSE LO/OVRAL® 30 mcg

each tablet contains 0.3 mg norgestrel with 0.03 mg ethinyl estradiol, Wyeth.

Oral contraceptive with a near-spotless record.

Wyeth Laboratories
Philadelphia, PA 19101

IN BRIEF:

Indications and Usage—LO/OVRAL® is indicated for the prevention of pregnancy in women who elect to use oral contraceptives (OC's) as a method of contraception.

Contraindications—OC's should not be used in women with any of the following conditions: 1. Thrombophlebitis or thromboembolic disorders. 2. A past history of deep-vein thrombophlebitis or thromboembolic disorders. 3. Cerebral-vascular or coronary-artery disease. 4. Known or suspected carcinoma of the breast. 5. Known or suspected estrogen-dependent neoplasia. 6. Undiagnosed abnormal genital bleeding. 7. Known or suspected pregnancy (see Warning No. 5). 8. Benign or malignant liver tumor which developed during use of OC's or other estrogen-containing products.

Warnings

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions, including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems*—An increased risk of thromboembolic and thrombotic disease associated with use of OC's is well established. Three principal studies in Great Britain and 3 in the U.S. have demonstrated increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic. These studies estimate that users of OC's are 4 to 11 times more likely than nonusers to develop these diseases without evident cause.

CEREBROVASCULAR DISORDERS—In a collaborative American study of cerebrovascular disorders in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers and the risk of thrombotic stroke was 4 to 9.5 times greater in users than in nonusers.

MYOCARDIAL INFARCTION (MI)—An increased risk of MI associated with use of OC's has been reported, confirming a previously suspected association. These studies, conducted in the UK, found, as expected, that the greater the number of underlying risk factors for coronary artery disease (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of pre-eclamptic toxemia) the higher the risk of developing MI, regardless of whether the patient was an OC user or not. OC's, however, were found to be a clear additional risk factor. In terms of relative risk, it has been estimated that OC users who do not smoke (smoking is considered a major predisposing condition to MI) are about twice as likely to have a fatal MI as nonusers who do not smoke. OC users who are also smokers have about a 5-fold increased risk of fatal MI compared to users who do not smoke, but about a 10- to 12-fold increased risk compared to nonusers who do not smoke. Furthermore, amount of smoking is also an important factor. In determining importance of these relative risks, however, baseline rates for various age groups must be given serious consideration. Importance of other predisposing conditions mentioned above in determining relative and absolute risks has not as yet been quantified; quite likely the same synergistic action exists, but perhaps to a lesser extent.

RISK OF DOSE—In an analysis of data derived from several national adverse-reaction reporting systems, British investigators concluded that risk of thromboembolism, including coronary thrombosis, is directly related to dose of estrogen in OC's. Preparations containing 100 mcg or more of estrogen were associated with higher risk of thromboembolism than those containing 50-80 mcg. Their analysis did suggest, however, that quantity of estrogen may not be the sole factor involved. This finding has been confirmed in the U.S.

ESTIMATE OF EXCESS MORTALITY FROM CIRCULATORY DISEASES—A large prospective study carried out in the UK estimated the mortality rate per 100,000 women per year from diseases of the circulatory system for users and nonusers of OC's according to age, smoking habits, and duration of use. Overall excess death rate annually from circulatory diseases for OC users was estimated to be 20 per 100,000 (ages 15-34—5/100,000; ages 35-44—33/100,000; ages 45-49—140/100,000), risk being concentrated in older women, in those with long duration of use, and in cigarette smokers. It was not possible, however, to examine interrelationships of age, smoking, and duration of use, nor to compare effects of continuous vs. intermittent use. Although the study showed a 10-fold increase in death due to circulatory diseases in users for 5 or more years, all these deaths occurred in women 35 or older. Until larger numbers of women under 35 with continuous use for 5 or more years are available, it is not possible to assess magnitude of relative risk for this younger group. Available data from a variety of sources have been analyzed to estimate risk of death associated with various methods of contraception. Estimates of risk of death for each method include combined risk of contraceptive method (e.g., thromboembolic and thrombotic disease in the case of OC's) plus risk attributable to pregnancy or abortion in event of method failure. This latter risk varies with effectiveness of method. The study concluded that mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of OC's in women over 40 who smoke. Lowest mortality is associated with condom or diaphragm backed up by early abortion. Risk of thromboembolic and thrombotic disease associated with OC's increases with age after about 30 and, for MI, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of pre-eclamptic toxemia, and especially cigarette smoking. Physician and patient should be alert to earliest manifestations of thromboembolic and thrombotic disorders (e.g., thrombophlebitis, pulmonary embolism, cerebrovascular insufficiency, coronary occlusion, retinal thrombosis, and mesenteric thrombosis). Should any of these occur or be suspected, the drug should be discontinued immediately.

A 4- to 6-fold increased risk of postsurgery thromboembolic complications has been reported in OC users.

If feasible, OC's should be discontinued at least 4 weeks before surgery of a type associated with increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions*—There have been reports of neuro-ocular lesions such as optic neuritis or retinal thrombosis associated with use of OC's. Discontinue OC's if there is unexplained, sudden or gradual, partial or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal-vascular lesions, and institute appropriate diagnostic and therapeutic measures.

3. *Carcinoma*—Long-term continuous administration of either natural or synthetic estrogen in certain animal species increases frequency of carcinoma of the breast, cervix, vagina, and liver. Certain synthetic progestogens, none currently contained in OC's, have been noted to increase incidence of mammary nodules, benign and malignant, in dogs. In humans, 3 case-control studies have reported an increased risk of endometrial carcinoma associated with prolonged use of exogenous estrogen in postmenopausal women. One publication reported on the first 21 cases submitted by physicians to a registry of cases of adenocarcinoma of the endometrium in women under 40 on OC's. Of cases found in women without predisposing risk factors (e.g., irregular bleeding at the time OC's were first given, polycystic ovaries), nearly all occurred in women who had used a sequential OC. These are no longer marketed. No evidence has been reported suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only OC's. Several studies have found no increase in breast cancer in women taking OC's or estrogens. One study, however, while also noting no overall increased risk of breast cancer in women on OC's, found an excess risk in subgroups of OC users with documented benign breast disease. Reduced occurrence of benign breast tumors in users of OC's has been well documented. In summary, there is at present no confirmed evidence from human studies of increased risk of cancer associated with OC's. Close clinical surveillance of all women on OC's is, nevertheless, essential. In all cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer or with breast nodules, fibrocystic disease, or abnormal mammograms should be monitored with particular care if they elect to use OC's.

4. *Hepatic Tumors*—Benign hepatic adenomas have been found to be associated with use of OC's. One study showed that OC's with high hormonal potency were associated with higher risk than lower potency OC's. Although benign, hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage. This has been reported in short-term as well as long-term users. Two studies relate risk with duration of use of OC's, the risk being much greater after 4 or more years' use. While hepatic adenoma is rare, it should be considered in women presenting abdominal pain and tenderness, abdominal mass or shock. A few cases of hepatocellular carcinoma have been reported in women on OC's. Relationship of these drugs to this type of malignancy is not known.

5. *Use in or Immediately Preceding Pregnancy, Birth Defects in Offspring, and Malignancy in Female Offspring*—Use of female sex hormones—both estrogenic and progestational agents—during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a nonsteroidal estrogen, have increased risk of developing in later life a form of vaginal or cervical cancer ordinarily extremely rare. This risk has been estimated to be of the order of 1 in 1,000 exposures or less. Although there is no evidence now that OC's further enhance risk of developing this type of malignancy, such patients should be monitored with particular care if they elect to use OC's. Furthermore, 30 to 90% of such exposed women have been found to have epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether this condition is a precursor of vaginal malignancy. Male children so exposed may develop abnormalities of the urogenital tract. Although similar data are not available with use of other estrogens, it cannot be presumed they would not induce similar changes. An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with use of sex hormones, including OC's, in pregnancy. One case-control study estimated a 4.7-fold increase in risk of limb-reduction defects in infants exposed in utero to sex hormones (OC's, hormonal withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some exposures involved only a few days. Data suggest that risk of limb-reduction defects in exposed fetuses is somewhat less than 1 in 1,000 live births. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well-controlled studies that progestogens are effective. There is some evidence that triploidy and possibly other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing OC's. Embryos with these anomalies are virtually always aborted spontaneously. Whether there is an overall increase in spontaneous abortion of pregnancies conceived soon after stopping OC's is unknown. It is recommended that, for any patient who has missed 2 consecutive periods, pregnancy should be ruled out before continuing OC's. If the patient has not adhered to the prescribed schedule, the possibility of pregnancy should be considered at time of first missed period, and further use of OC's should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus, and advisability of continuation of the pregnancy should be discussed. It is also recommended that women who discontinue OC's with intent of becoming pregnant use an alternate form of contraception for a period of time before attempting to conceive. Many clinicians recommend 3 months, although no precise information is available on which to base this. The administration of progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease*—Studies report increased risk of surgically confirmed gallbladder disease in users of OC's and estrogens. In one study, increased risk appeared after 2 years' use and doubled after 4 or 5 years' use. In one of the other studies, increased risk was apparent between 6 and 12 months' use.

7. *Carbohydrate and Lipid Metabolic Effects*—Decrease in glucose tolerance has been observed in a significant percentage of patients on OC's. For this reason, prediabetic and diabetic patients should be carefully observed while on OC's. Increase in triglycerides and total phospholipids has been observed in patients on OC's; clinical significance of this finding remains to be defined.

8. *Elevated Blood Pressure*—Increase in blood pressure has been reported in patients on OC's. In some women, hypertension may occur within a few months of beginning OC's. In the 1st year of use, prevalence of women with hypertension is low in users and may be no higher than that of a comparable group of nonusers. Prevalence in users increases, however, with longer exposure, and in the 5th year of use is 2½ to 3 times the reported prevalence in the 1st year. Age is also strongly correlated with development of hypertension in OC users. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure on OC's. Hypertension that develops as a result of taking OC's usually returns to normal after discontinuing the drug.

9. *Headache*—Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of OC's and evaluation of the cause.

10. *Bleeding Irregularities*—Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing OC's. In breakthrough bleeding, as in all cases of irregular vaginal bleeding, nonfunctional causes should be borne in mind. In undiagnosed persistent or recurrent abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy. If pathology has been excluded, time or change to another OC may solve the problem. Changing to an OC with a higher estrogen content, while potentially useful in minimizing menstrual irregularity, should be done only if necessary, since this may increase risk of thromboembolic disease. Women with past history of oligomenorrhea or secondary amenorrhea or young women without regular cycles may have a tendency to remain anovulatory or to become amenorrheic after discontinuing OC's. Women with these pre-existing problems should be advised of this possibility and encouraged to use other methods. Post-use anovulation, possibly prolonged, may also occur in women without previous irregularities.

11. *Ectopic Pregnancy*—Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-feeding*—OC's given in the postpartum period may interfere with lactation and decrease quantity and quality of breast milk. Furthermore, a small fraction of the hormones in OC's has been identified in the milk of mothers on OC's; effects, if any, on the breast-fed child have not been determined. If feasible, defer OC's until infant has been weaned.

Precautions—GENERAL—1. A complete medical and family history should be taken prior to initiation of OC's. Pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen and pelvic organs, including Pap smear and relevant laboratory tests. As a general rule OC's should not be prescribed for longer than 1 year without another physical examination.

2. Under influence of estrogen-progestogen preparations, pre-existing uterine leiomyomata may increase in size.

3. Patients with history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree. Patients becoming significantly depressed while on OC's should stop OC's and use an alternate method to try to determine whether the symptom is drug-related.

4. OC's may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention, such as convulsive disorders, migraine syndrome, asthma, or cardiac or renal insufficiency.

5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence while on OC's. If jaundice develops, OC's should be discontinued.

6. Steroid hormones may be poorly metabolized in patients with impaired liver function and should be administered with caution.

7. OC users may have disturbances in normal tryptophan metabolism which may result in a relative pyridoxine deficiency. Clinical significance is undetermined.

8. Serum folate levels may be depressed by OC's. Since the pregnant woman is predisposed to development of folate deficiency and incidence of folate deficiency increases with increasing gestation, it is possible that if a woman becomes pregnant shortly after stopping OC's, she may have a greater chance of developing folate deficiency and complications attributed to this deficiency.

9. The pathologist should be advised of OC therapy when relevant specimens are submitted.

10. Certain endocrine- and liver-function tests and blood components may be affected by estrogen-containing OC's: a. Increased sulfobromophthalein retention. b. Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. c. Increased thyroid-binding globulin (TBG) leading to increased circulating total-thyroid hormone, as measured by protein-bound iodine (PBI), T4 by column, or T4 by radioimmunoassay. Free T3 resin uptake is decreased, reflecting the elevated TBG; free T4 concentration is unaltered. d. Decreased pregnanediol excretion. e. Reduced response to metyrapone test.

Information for the Patient—See Patient Package Labeling.

Drug Interactions—Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, ampicillin and tetracycline.

Carcinogenesis—See Warnings on carcinogenic potential of OC's.

Pregnancy—Category X. See Contraindications, Warnings.

Nursing Mothers—See Warnings.

Adverse Reactions—An increased risk of these serious adverse reactions has been associated with use of OC's (see Warnings): thrombophlebitis, pulmonary embolism, coronary thrombosis, cerebral thrombosis, cerebral hemorrhage, hypertension, gallbladder disease, benign hepatomas, congenital anomalies. There is evidence of an association between the following conditions and use of OC's although additional confirmatory studies are needed: mesenteric thrombosis, neuro-ocular lesions, e.g., retinal thrombosis and optic neuritis.

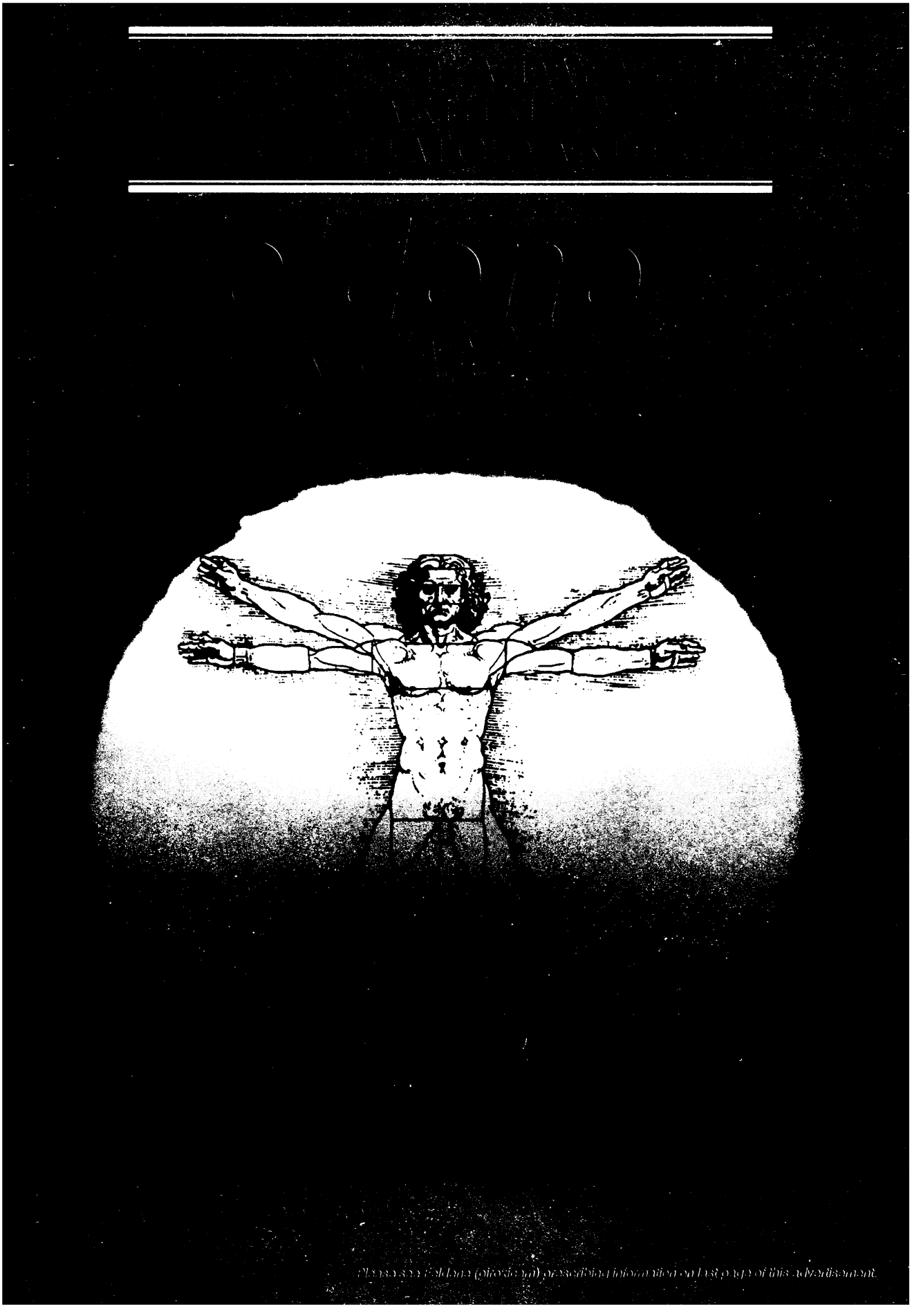
The following adverse reactions have been reported in patients on OC's and are believed to be drug-related. Nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10 percent or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally. Gastrointestinal symptoms (such as abdominal cramps and bloating); breakthrough bleeding, spotting, change in menstrual flow; dysmenorrhea, amenorrhea during and after treatment, temporary infertility after discontinuance of treatment; edema; chloasma or melasma which may persist; breast changes: tenderness, enlargement, and secretion; change in weight (increase or decrease); change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature (steepening), intolerance to contact lenses.

The following adverse reactions have been reported in users of OC's, and the association has been neither confirmed nor refuted: premenstrual-like syndrome, cataracts, changes in libido, chorea, changes in appetite, cystitis-like syndrome, headache, nervousness, dizziness, hirsutism, loss of scalp hair, erythema multiforme, erythema nodosum, hemorrhagic eruption, vaginitis, porphyria.

Acute Overdose—Serious ill effects have not been reported following acute ingestion of large doses of OC's by young children. Overdosage may cause nausea, and withdrawal bleeding may occur in females.

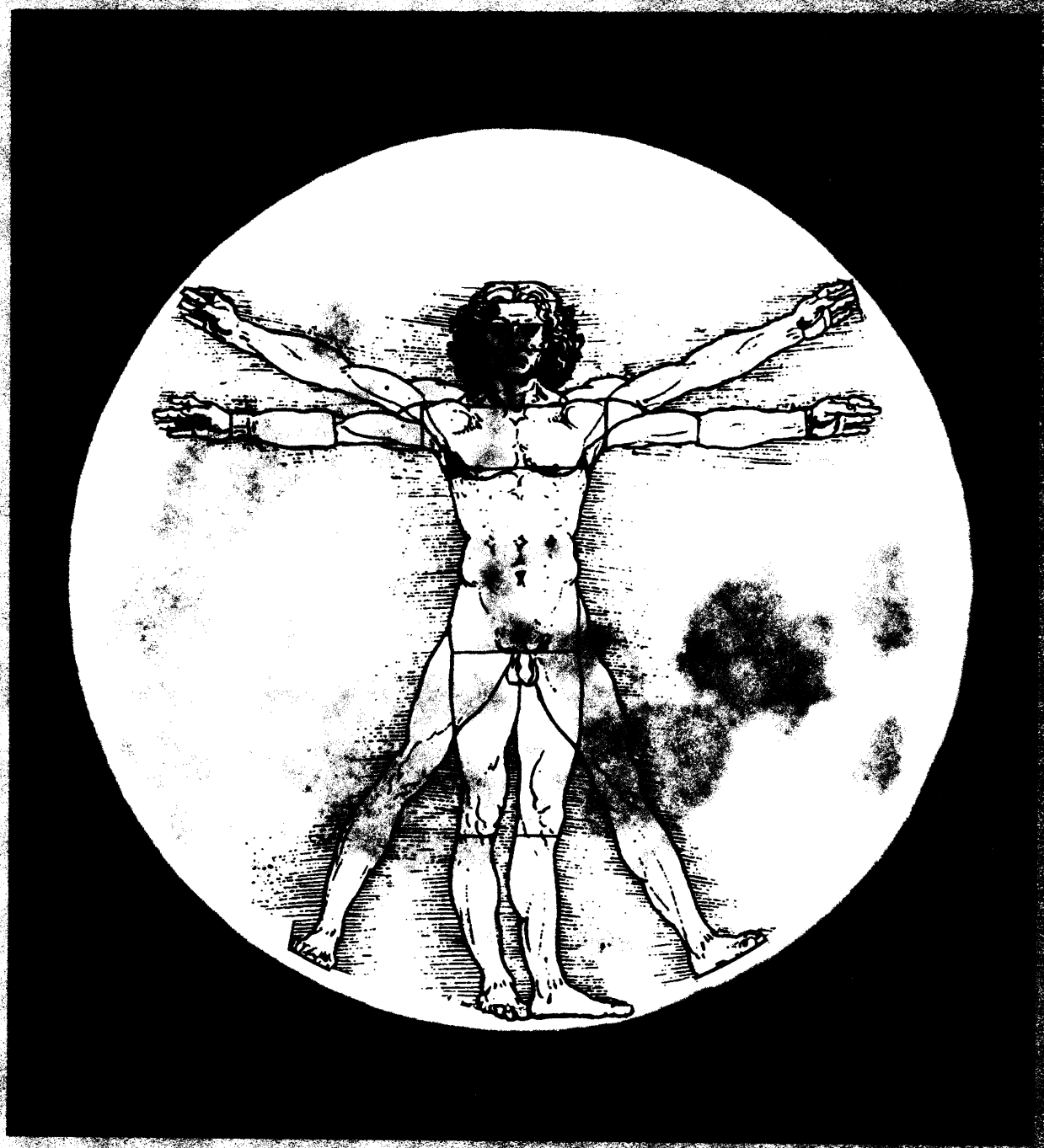
LO/OVRAL® each tablet contains 0.3 mg norgestrel with 0.03 mg ethinyl estradiol.

Wyeth Laboratories, Phila., Pa. 19101

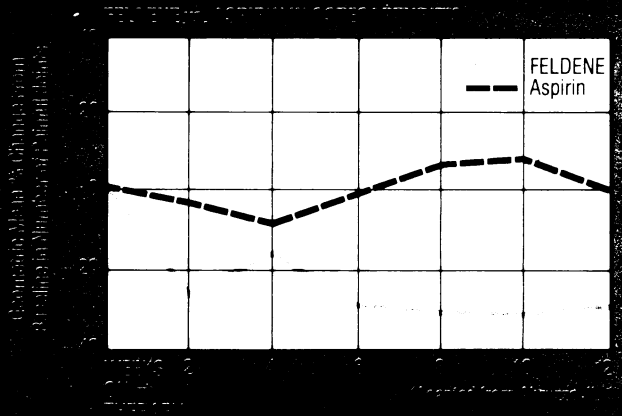


Please see reverse (obverse?) for prescribing information on last page of this advertisement.

ALL-DAY, ALL-NIGHT ARTHRITIS CONTROL WITH ONE CAPSULE



ALL-NIGHT CONTROL

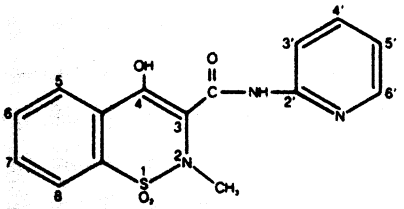


	Percent of patients, **FELDENE** was	
PREVIOUS DRUG	BETTER THAN	NUMBER OF PATIENTS
IBUPROFEN	71%	79
INDOMETHACIN	69%	206
ASPIRIN	88%	50
NAPROXEN	54%	41
SULINDAC	60%	35
PHENYLBUTAZONE	62%	29
TOLMETIN	75%	16
ALL OTHERS*	79%	293
ALL DRUGS	72%	749

* Please see Feldene (piroxicam) prescribing information on last page of this advertisement.

FELDENE® CAPSULES
(piroxicam)
For Oral Use

DESCRIPTION. FELDENE (piroxicam) is 4-Hydroxy-2-methyl-*N*-2-pyridinyl-2*H*-1,2-benzothiazine-3-carboxamide 1,1-dioxide, an oxicam. Members of the oxicam family are not carboxylic acids, but they are acidic by virtue of the enolic 4-hydroxy substituent. FELDENE occurs as a white crystalline solid, sparingly soluble in water, dilute acid and most organic solvents. It is slightly soluble in alcohols and in aqueous alkaline solution. It exhibits a weakly acidic 4-hydroxy proton (pKa 5.1) and a weakly basic pyridyl nitrogen (pKa 1.8). It has the following structure:



Molecular Formula: $C_{15}H_{13}N_3O_4S$ Molecular Weight: 331.35

CLINICAL PHARMACOLOGY. FELDENE has shown anti-inflammatory, analgesic and antipyretic properties in animals. Edema, erythema, tissue proliferation, fever, and pain can all be inhibited in laboratory animals by the administration of FELDENE. It is effective regardless of the etiology of the inflammation. The mode of action of FELDENE is not fully established at this time. However, a common mechanism for the above effects may exist in the ability of FELDENE to inhibit the biosynthesis of prostaglandins, known mediators of inflammation.

It is established that FELDENE does not act by stimulating the pituitary-adrenal axis.

FELDENE is well absorbed following oral administration. Drug plasma concentrations are proportional for 10 and 20 mg doses, generally peak within three to five hours after medication, and subsequently decline with a mean half-life of 50 hours (range of 30 to 86 hours, although values outside of this range have been encountered).

This prolonged half-life results in the maintenance of relatively stable plasma concentrations throughout the day on once daily doses and to significant drug accumulation upon multiple dosing. A single 20 mg dose generally produces peak piroxicam plasma levels of 1.5 to 2 mcg/ml, while maximum drug plasma concentrations, after repeated daily ingestion of 20 mg FELDENE, usually stabilize at 3-8 mcg/ml. Most patients approximate steady state plasma levels within 7 to 12 days. Higher levels, which approximate steady state at two to three weeks, have been observed in patients in whom longer plasma half-lives of piroxicam occurred.

FELDENE and its biotransformation products are excreted in urine and feces, with about twice as much appearing in the urine as the feces. Metabolism occurs by hydroxylation at the 5 position of the pyridyl side chain and conjugation of this product; by cyclodehydration; and by a sequence of reactions involving hydrolysis of the amide linkage, decarboxylation, ring contraction, and N-demethylation. Less than 5% of the daily dose is excreted unchanged.

Concurrent administration of aspirin (3900 mg/day) and FELDENE (20 mg/day), resulted in a reduction of plasma levels of piroxicam to about 80% of their normal values. The use of FELDENE in conjunction with aspirin is not recommended because data are inadequate to demonstrate that the combination produces greater improvement than that achieved with aspirin alone and the potential for adverse reactions is increased. Concomitant administration of antacids had no effect on FELDENE plasma levels. The effects of impaired renal function or hepatic disease on plasma levels have not been established.

FELDENE, like salicylates and other nonsteroidal anti-inflammatory agents, is associated with symptoms of gastrointestinal tract irritation (see ADVERSE REACTIONS). However, in a study utilizing ^{51}Cr-tagged red blood cells, 20 mg of FELDENE administered as a single dose for four days did not result in a significant increase in fecal blood loss and did not detectably affect the gastric mucosa. In the same study a total daily dose of 3900 mg of aspirin, i.e., 972 mg q.i.d., caused a significant increase in fecal blood loss and mucosal lesions as demonstrated by gastroscopy.

In controlled clinical trials, the effectiveness of FELDENE has been established for both acute exacerbations and long-term management of rheumatoid arthritis and osteoarthritis.

The therapeutic effects of FELDENE are evident early in the treatment of both diseases with a progressive increase in response over several (8-12) weeks. Efficacy is seen in terms of pain relief and, when present, subsidence of inflammation.

Doses of 20 mg/day FELDENE display a therapeutic effect comparable to therapeutic doses of aspirin, with a lower incidence of minor gastrointestinal effects and tinnitus.

FELDENE has been administered concomitantly with fixed doses of gold and corticosteroids. The existence of a "steroid-sparing" effect has not been adequately studied to date.

INDICATIONS AND USAGE. FELDENE is indicated for acute or long-term use in the relief of signs and symptoms of the following:

1. osteoarthritis
2. rheumatoid arthritis

Dosage recommendations for use in children have not been established.

CONTRAINDICATIONS. FELDENE should not be used in patients who have previously exhibited hypersensitivity to it, or in individuals with the syndrome comprised of bronchospasm, nasal polyps, and angioedema precipitated by aspirin or other nonsteroidal anti-inflammatory drugs.

WARNINGS. Peptic ulceration, perforation, and G.I. bleeding—sometimes severe, and, in rare instances fatal—have been reported with patients receiving FELDENE. If FELDENE must be given to patients with a history of upper gastrointestinal tract disease, the patient should be under close supervision (see ADVERSE REACTIONS). In controlled clinical trials, incidence of peptic ulceration with the maximum recommended FELDENE capsule dose of 20 mg per day was 0.8%. The use of doses higher than the recommended dose is associated with an increase in the incidence of gastrointestinal irritation and ulcers.

PRECAUTIONS. As with other anti-inflammatory agents, long-term administration to animals results in renal papillary necrosis and related pathology in rats, mice, and dogs.

As with other drugs that inhibit prostaglandin biosynthetase, reversible elevations of BUN have been reported in clinical studies with FELDENE. The effect is thought to result from inhibition of renal prostaglandin synthesis resulting in a change in medullary and deep cortical blood flow with an attendant effect on renal function. Because of the extensive renal excretion of piroxicam, patients with impaired renal function should be carefully monitored.

Although other nonsteroidal anti-inflammatory drugs do not have the same direct effects on platelets that aspirin does, all drugs inhibiting prostaglandin biosynthesis do interfere with platelet function to some degree; therefore, patients who may be adversely affected by such an action should be carefully observed when FELDENE is administered.

Because of reports of adverse eye findings with nonsteroidal anti-inflammatory agents, it is recommended that patients who develop visual complaints during treatment with FELDENE have ophthalmic evaluation.

As with other nonsteroidal anti-inflammatory drugs, borderline elevations of one or more liver tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy. The SGPT (ALT) test is probably the most sensitive indicator of liver dysfunction. Meaningful (3 times the upper limit of normal) elevations of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of more severe hepatic reaction while on therapy with FELDENE. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with other nonsteroidal anti-inflammatory drugs. Although such reactions are rare, if abnormal liver tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), FELDENE should be discontinued. (See also ADVERSE REACTIONS.)

Less than 1.0% of patients receiving FELDENE (piroxicam) have shown reversible elevation of one or more liver function parameters. While concurrent aspirin may have been involved in some of these changes, a relationship to FELDENE could not be excluded. Studies in patients with impaired liver function have not been done.

Although at the recommended dose of 20 mg/day of FELDENE increased fecal blood loss due to gastrointestinal irritation did not occur (see CLINICAL PHARMACOLOGY), in about 4% of the patients treated with FELDENE alone or concomitantly with aspirin, reductions in hemoglobin and hematocrit values were observed. Therefore, these values should be determined if signs or symptoms of anemia occur.

Peripheral edema has been observed in approximately 2% of the patients treated with FELDENE. Therefore, as with other nonsteroidal anti-inflammatory drugs, FELDENE should be used with caution in patients with compromised cardiac function, hypertension or other conditions predisposing to fluid retention.

DRUG INTERACTIONS. FELDENE is highly protein bound, and, therefore, might be expected to displace other protein-bound drugs. Although *in vitro* studies have shown this not to occur with dicoumarol, physicians should closely monitor patients for a change in dosage requirements when administering FELDENE to patients on coumarin-type anticoagulants and other highly protein-bound drugs.

Plasma levels of piroxicam are depressed to approximately 80% of their normal values when FELDENE is administered in conjunction with aspirin (3900 mg/day), but concomitant administration of antacids has no effect on piroxicam plasma levels (see CLINICAL PHARMACOLOGY).

Carcinogenesis, Chronic Animal Toxicity and Impairment of Fertility: Subacute and chronic toxicity studies have been carried out in rats, mice, dogs, and monkeys.

The pathology most often seen was that characteristically associated with the animal toxicology of anti-inflammatory agents: renal papillary necrosis (see PRECAUTIONS) and gastrointestinal lesions.

In classical studies in laboratory animals piroxicam did not show any teratogenic potential.

Reproductive studies revealed no impairment of fertility in animals.

Pregnancy and Nursing Mothers: Like other drugs which inhibit the synthesis and release of prostaglandins, piroxicam increased the incidence of dystocia and delayed parturition in pregnant animals when piroxicam administration was continued late into pregnancy. Gastrointestinal tract toxicity was increased in pregnant females in the last trimester of pregnancy compared to non-pregnant females or females in earlier trimesters of pregnancy.

FELDENE is not recommended for use in nursing mothers or in pregnant women because of the animal findings and since safety for such use has not been established in humans.

Use in Children: Dosage recommendations and indications for use in children have not been established.

ADVERSE REACTIONS. The incidence of adverse reactions to piroxicam is based on clinical trials involving approximately 2300 patients, about 400 of whom were treated for more than one year and 170 for more than two years. About 30% of all patients receiving daily doses of 20 mg of FELDENE experienced side effects. Gastrointestinal symptoms were the most prominent side effects—occurring in approximately 20% of the patients, which in most instances did not interfere with the course of therapy. Of the patients experiencing gastrointestinal side effects, approximately 5% discontinued therapy with an overall incidence of peptic ulceration of about 1%.

Other than the gastrointestinal symptoms, edema, dizziness, headache, changes in hematological parameters, and rash have been reported in a small percentage of patients. Routine ophthalmoscopy and slit-lamp examinations have revealed no evidence of ocular changes in 205 patients followed from 3 to 24 months while on therapy.

Adverse reactions are listed below by body system for all patients in clinical trials with FELDENE at doses of 20 mg/day.

Incidence Greater Than 1% The following adverse reactions occurred more frequently than 1 in 100.

Gastrointestinal: stomatitis, anorexia, epigastric distress*, nausea*, constipation, abdominal discomfort, flatulence, diarrhea, abdominal pain, and indigestion.

Hematological: decreases in hemoglobin* and hematocrit* (see PRECAUTIONS), leucopenia, eosinophilia.

Urogenital: BUN elevations (see PRECAUTIONS)

Central Nervous System: dizziness, somnolence, vertigo

Special Senses: tinnitus

Body as a Whole: headache, malaise

Cardiovascular/Respiratory: edema (see PRECAUTIONS)

Dermatologic: pruritus, rash

*Reactions occurring in 3% to 6% of patients treated with FELDENE.

Incidence Less Than 1% (Causal Relationship Probable)

The following adverse reactions occurred less frequently than 1 in 100. The probability exists that there is a causal relationship between FELDENE and these reactions.

Gastrointestinal: liver function abnormalities (see PRECAUTIONS), vomiting, hematemesis, melena, gastrointestinal bleeding, perforation and ulceration, and dry mouth

Hematological: thrombocytopenia

Dermatologic: sweating, erythema, bruising, desquamation, erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, photoallergic skin reactions

Special Senses: swollen eyes, blurred vision, eye irritations

Body as a Whole: pain (colic)

Cardiovascular/Respiratory: hypertension (see PRECAUTIONS)

Urogenital: hematuria

Metabolic: hypoglycemia, weight increase, weight decrease

Central Nervous System: depression, insomnia, nervousness

Incidence Less Than 1% (Causal Relationship Unknown)

Other adverse reactions were reported with a frequency of less than 1 in 100, but a causal relationship between FELDENE and the reaction could not be determined.

Cardiovascular/Respiratory: palpitations, dyspnea

Central Nervous System: akathisia

Urogenital System: dysuria

Hematological: aplastic anaemia

OVERDOSAGE. In the event treatment for overdosage is required the long plasma half-life (see CLINICAL PHARMACOLOGY) of piroxicam should be considered. The absence of experience with acute overdosage precludes characterization of sequelae and recommendation of specific antidotal efficacy at this time. It is reasonable to assume, however, that the standard measures of gastric evacuation and general supportive therapy would apply.

ADMINISTRATION AND DOSAGE. Rheumatoid Arthritis, Osteoarthritis:

It is recommended that FELDENE therapy be initiated and maintained at a single daily dose of 20 mg. If desired, the daily dose may be divided. Because of the long half-life of FELDENE, steady-state blood levels are not reached for 7-12 days. Therefore, although the therapeutic effects of FELDENE are evident early in treatment, there is a progressive increase in response over several weeks and the effect of therapy should not be assessed for two weeks.

Dosage recommendations and indications for use in children have not been established.

HOW SUPPLIED. FELDENE Capsules for oral administration.

Bottles of 100: 10 mg (NDC 0069-3220-66) maroon and blue #322
20 mg (NDC 0069-3230-66) maroon #323

Bottles of 500: 20 mg (NDC 0069-3230-73) maroon #323

Unit dose packages of 100: 20 mg (NDC 0069-3230-41) maroon #323

Revised November 19[illegible]

References:

1. Abruzzo JL, Gordon GV, Meyers AR: Double-blind study comparing piroxicam and aspirin in the treatment of osteoarthritis. *Am J Med* (report) 72:45–49, February 16, 1982.
2. Willkens RF, Ward JR, Louie JS, et al: Double-blind study comparing piroxicam and aspirin in the treatment of rheumatoid arthritis. *Am J Med* (report) 72:23–26, February 16, 1982.
3. Dessain P: Efficacy and toleration of piroxicam in general practice: A multicenter study of osteoarthritis. *Postgrad Med* (special report), 76–81, April, 1982.

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Beatrice Terry

That's because, unlike Encare, SEMICID® does not effervesce. In some instances, however, slight irritation may accompany product use.

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SEMICID is convenient. It is inserted digitally—no applicator is needed so there's no mess.

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SEMICID requires no individualized fitting. It is simple to use, unobtrusive and does not compromise spontaneity. It can be inserted up to one hour ahead, but must be inserted at least 15 minutes before intercourse according to package instructions. When used as directed, SEMICID forms an effective physical and spermicidal barrier.

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SEMICID has a high degree of efficacy and a two-year continuation rate of 80% that's proven in clinical data.* SEMICID is safe. It eliminates the potential for systemic risks, since it is neither a systemic drug nor a device. SEMICID is approximately as effective as vaginal foam contraceptives in actual use, but is not as effective as the pill or IUD. It contains nonoxynol-9, the spermicide that's been used successfully by millions of women for over 10 years.

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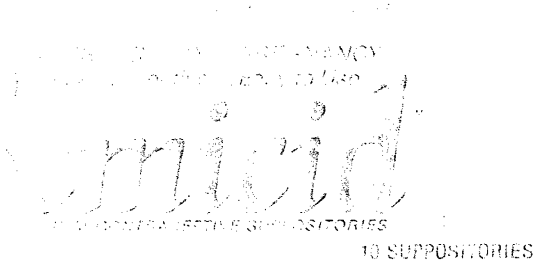

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*Squire JJ, Berger GS, Keith L. A retrospective clinical study of a vaginal contraceptive suppository. J Reprod Med 22:319-323, June 1979.

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"I have been able to do volunteer work...and feel needed and useful once again."

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1) Confirmed vasospastic angina.
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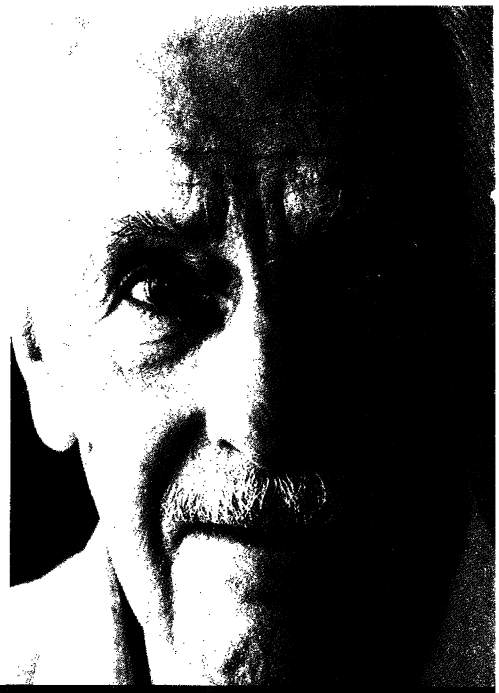
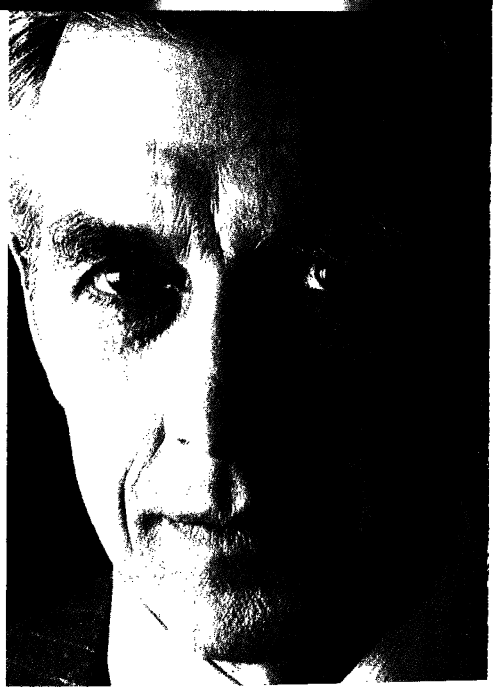
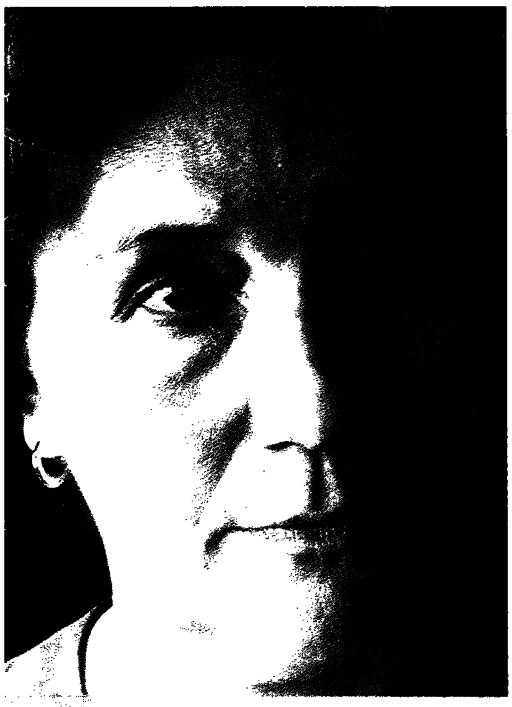
Arthritis pain after fifty





Age is no barrier to the benefits of Motrin® 600 mg tablets



The pain-relieving power of *Motrin* 600 mg tablets is welcome at any age. The advantages of *Motrin* become more important as patients grow older.

- ***Motrin* is as effective as indomethacin** in relieving arthritis pain and inflammation. *Motrin* causes significantly fewer CNS effects and about half as many GI complaints as indomethacin.
- ***Motrin* relieves pain as effectively as a combination of aspirin 650 mg plus codeine 60 mg,** as documented in analgesia studies.
- ***Motrin* has no significant effect on clotting factors in patients on coumarin-type anticoagulants** in controlled studies. *Motrin* should be used with caution in persons with intrinsic coagulation defects and in those on anticoagulant therapy.
- ***Motrin* may be taken with meals or between meals... with or without antacids.**
- ***Motrin* is rapidly metabolized and does not accumulate.** *Motrin* provides better control of therapy, rapid response to dosage adjustment, and permits tailoring dosage to each patient's needs.

The confidence that comes from experience... good reason to prescribe

Motrin® 600 mg TABLETS

ibuprofen

One tablet t.i.d.

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In the treatment of insomnia

Good mornings start with restful nights.

Dalmane *(flurazepam HCl/Roche)* patients fall asleep faster, sleep longer and seldom awaken with morning hangover.

Feeling well rested in the morning usually means having slept well the night before. And for insomniac patients receiving hypnotic therapy, a good morning also means awakening with few side effects from their medication. Many physicians choose Dalmane for their patients who suffer from insomnia for this very reason.

Aside from enabling patients to fall asleep more quickly and sleep longer, Dalmane seldom causes morning hangover. Most Dalmane patients feel alert and refreshed when they awaken. In 53 paired-night clinical studies comparing Dalmane and placebo in 2010 insomniac patients with a variety of secondary diagnoses, most Dalmane patients awakened more alert and refreshed, and less groggy and drowsy, than on nights when they had taken only placebo.[1] In a double-blind crossover study of 42 patients in private practice, approximately three times as many patients reported feeling refreshed and alert upon awakening after a night on Dalmane (flurazepam HCl/Roche) compared to placebo nights.[2] This difference was highly significant ($p<0.001$). And a retrospective study of 2542 hospitalized patients who received Dalmane revealed only a 3.1% incidence of side effects.[3]

While residual effects from Dalmane therapy are infrequent, patients should be cautioned about drinking alcohol, driving or operating hazardous machinery after ingesting the drug.

Efficacy and safety in a broad range of patient types.

Over 2000 clinical trials involving more than 10,000 patients have shown that Dalmane patients fall asleep sooner, sleep longer and experience fewer nocturnal awakenings.[4] The safety and efficacy of Dalmane have been demonstrated in medical and surgical hospitalized patients, in patients seen in office practice and in elderly patients.[5-8] Since the risk of oversedation, dizziness, confu-

sion and/or ataxia increases with larger doses in the elderly, it is recommended that the dosage be limited to 15 mg.

Moreover, the efficacy and safety of Dalmane for the treatment of insomnia have been demonstrated in thousands of patients with a variety of primary medical conditions, including cardiovascular, neuropsychiatric, endocrine-metabolic, gastrointestinal, genitourinary, respiratory and musculoskeletal disorders.[1] Dalmane (flurazepam HCl/Roche) is contraindicated in pregnancy and in patients hypersensitive to the drug.

Avoids rebound insomnia upon discontinuation.

Rebound insomnia—a worsening of sleep beyond pretherapy levels after drug discontinuation—has been reported as a potential clinical problem with some hypnotics.[9,10] However, this problem has not been reported with Dalmane. In eight out of eight sleep laboratory studies, there were no reports of rebound insomnia.[11] When you prescribe Dalmane, you can be confident of efficacy that enhances therapeutic progress. Your insomniac patients can be assured of a restful night, night after night—a good start for a good morning.

References: 1. Data on file, Hoffmann-La Roche Inc., Nutley, NJ. **2.** Zimmerman AM: *Curr Ther Res 13*:18-22, Jan 1971. **3.** Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther 21*:355-361, Mar 1977. **4.** Data on file, Hoffmann-La Roche Inc., Nutley, NJ. **5.** Meyer JA, Kurland KZ: *Milit Med 138*:471-474, Aug 1973. **6.** Feffer HL, Gibbons B: *Med Times 101*(8):130-135, Aug 1973. **7.** Jacobson A *et al*: *Psychophysiology 7*:345, Sep 1970. **8.** Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc 27*:541-546, Dec 1979. **9.** Kales A, Scharf MB, Kales JD: *Science 201*:1039-1041, Sep 1978. **10.** Kales A *et al*: *JAMA 241*:1692-1695, Apr 1979. **11.** Monti JM: *Methods Find Exp Clin Pharmacol 3*(5):303-326, 1981.

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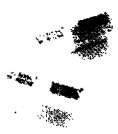

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Please see following page for summary of product information.

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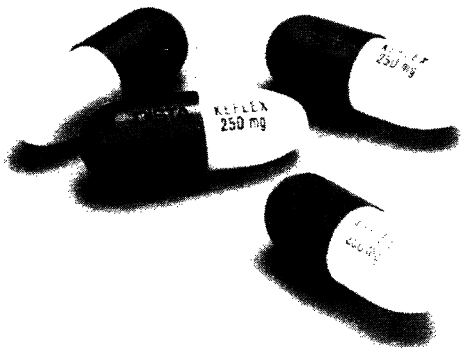

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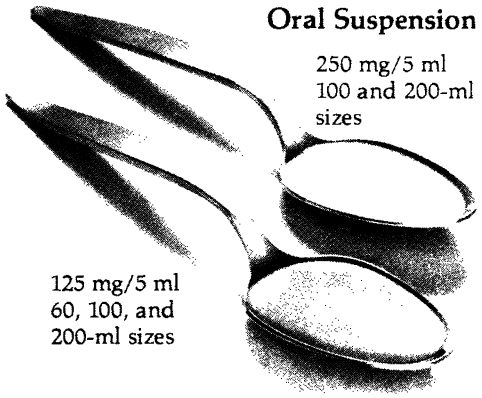

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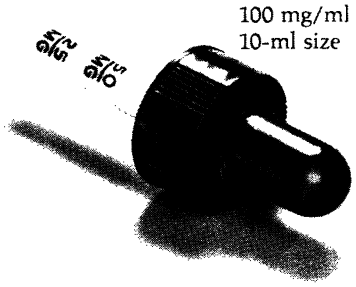

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THE SPASM/PAIN/SPASM CYCLE

In skeletal muscle spasm due to local pathology, responsive to the distinct actions of

Adjunctive VALIUM® (IV) diazepam/Roche

2-mg, 5-mg, 10-mg scored tablets

Advantages cyclobenzaprine cannot claim

—Wider range of indications as adjunctive therapy for skeletal muscle spasm—from spasm due to local pathology (e.g., herniated lumbosacral discs or acute muscle strain) to spasm associated with upper motor neuron disorders (e.g., cerebral palsy, athetosis, stiff-man syndrome).

—May be used adjunctively for relieving skeletal muscle spasm in patients with hyperthyroidism, cardiac patients and patients being treated with anticholinergics or guanethidine-type antihypertensives.

—Can be administered to patients less than 15 years and more than 6 months of age.

—Scored tablets in three strengths provide greater dosage flexibility.

Since drowsiness, fatigue and ataxia sometimes occur, patients should be cautioned against driving or operating hazardous machinery and should also be advised against simultaneous ingestion of alcohol.

References: 1. Rankin EA: *Clin Ed J* 31:46-50, Jan 1975. 2. [illegible] spasm relaxes your patient. *Patient Care* 8:120, June 1974.

Before prescribing, please consult complete product information, a summary of which follows:

Indications:

Contraindicated:

Warnings:

Usage in Pregnancy: **Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.**

Precautions:

Side Effects:

Dosage:

How Supplied:

ROCHE

BACK AGAIN

the spasm/pain/spasm cycle

Skeletal muscle spasm tends to recur—usually because predisposing factors (such as muscle weakness, faulty posture and obesity) remain uncorrected, so that even minor trauma may set off painful spasm.[1,2] The key to therapeutic relief is to stop the spasm. In some patients with skeletal muscle spasm who also experience excessive anxiety, Valium® (diazepam/Roche) provides a unique dual advantage— it is indicated for the management of anxiety disorders and also adjunctively for the relief of muscle spasm due to local pathology.

For skeletal muscle spasm due to local pathology

Adjunctive

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